IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TEXARKANA DIVISION

HEALTH CHOICE ALLIANCE, LLC, on behalf of the UNITED STATES OF AMERICA; STATE OF ARKANSAS; STATE OF CALIFORNIA; STATE OF COLORADO; STATE OF CONNECTICUT; STATE OF DELAWARE; DISTRICT OF COLUMBIA; STATE OF FLORIDA; STATE OF GEORGIA; STATE OF HAWAII; STATE OF ILLINOIS; STATE OF INDIANA; STATE OF IOWA; STATE OF LOUISIANA; STATE OF MARYLAND; COMMONWEALTH OF MASSACHUSETTS; STATE OF MICHIGAN; STATE OF MINNESOTA; STATE OF MONTANA; STATE OF NEVADA; STATE OF NEW HAMPSHIRE; STATE OF NEW JERSEY; STATE OF NEW MEXICO; STATE OF NEW YORK; STATE OF NORTH CAROLINA; STATE OF OKLAHOMA; STATE OF RHODE ISLAND; STATE OF TENNESSEE; STATE OF TEXAS; STATE OF VERMONT; COMMONWEALTH OF VIRGINIA; and STATE OF WASHINGTON,

Plaintiffs/Relator;

v.

ELI LILLY AND COMPANY, INC.; HEALTHSTAR CLINICAL EDUCATION SOLUTIONS LLC; VMS BIOMARKETING; COVANCE, INC.; and UNITED BIOSOURCE CORPORATION,

Defendants.

Civil Action No.: 5:17-CV-123-RWS-CMC

FIRST AMENDED COMPLAINT AND JURY DEMAND

The United States of America (the "United States") and the Plaintiff States (the United States and Plaintiff States are collectively referred to herein as the "Government"), by and through their *qui tam* Relator Health Choice Alliance, LLC (the "Relator"), allege:

PRELIMINARY STATEMENT

1. This is a civil action brought on behalf of the Government under the Federal False Claims Act, 31 U.S.C. § 3729 – 3733 (the "False Claims Act" or "FCA") and the false claims acts of the respective Plaintiff States[1] to recover treble damages sustained by and civil penalties

[1] The state statues are the: (1) Arkansas Medicaid Fraud False Claims Act, Ark. Code Ann. §§ 20-77-901 – 911 (as amended by 2017 Arkansas Laws Act 978 (S.B. 564)); (2) California False Claims Act, Cal. Gov't Code §§ 12650 – 12656; (3) Colorado Medicaid False Claims Act, Colo. Rev. Stat. Ann. §§ 25.5-4-303.5 – 4-310; (4) Connecticut False Claims and Other Prohibited Acts Under State-Administered Health or Human Services Programs Act, Conn. Gen. Stat. Ann. §§ 4-274 – 289; (5) Delaware False Claims and Reporting Act, Del. C. Ann. tit. 6, §§ 1201 – 1211; (6) District of Columbia Medicaid Fraud Enforcement and Recovery Amendment Act of 2012, D.C. Code Ann. §§ 2-381.01 – 381.10; (7) Florida False Claims Act, Fla. Stat. Ann. §§ 68.081 – 68.092; (8) Georgia False Medicaid Claims Act, Ga. Code Ann. §§ 49-4-168 – 4-168.6; (9) Hawaii False Claims to the State Act, Haw. Rev. Stat. Ann. §§ 661-21 – 31; (10) Illinois False Claims Act, 740 Ill. Comp. Stat. Ann. §§ 175/1 – 175/8; (11) Indiana False Claims and Whistleblower Protection Act, Ind. Code Ann. §§ 5-11-5.5-1 – 5.5-18; (12) Iowa False Claims Act, Iowa Code Ann. §§ 685.1 – 685.7; (13) Louisiana Medical Assistance Programs Integrity Law, La. Stat. Ann. §§ 437.1 – 440.16; (14) Maryland False Claims Act, Md. Code Ann. Health-Gen. §§ 8-101 – 111; (15) Massachusetts False Claims Law, Mass. Gen. Laws Ann. ch. 12, §§ 5A – 5O; (16) Michigan Medicaid False Claim Act, Mich. Comp. Laws Ann. §§ 400.601 – 400.615; (17) Minnesota False Claims Act, Minn. Stat. Ann. §§ 15C.01 – 15C.16; (18) Montana False Claims Act, Mont. Code Ann. §§ 17-8-401 – 416; (19) Nevada Submission of False Claims to State or Local Government Act, Nev. Rev. Stat. Ann. §§ 357.010 – 357.250; (20) New Hampshire Medicaid Fraud and False Claims Act, N.H. Rev. Stat. Ann. §§ 167:61-b – 61-e; (21) New Jersey False Claims Act, N.J. Stat. Ann. §§ 2A:32C-1 – 32C-18; (22) New Mexico Medicaid False Claims Act, N.M. Stat. Ann. §§ 27-14-1 – 14-15; (23) New Mexico Fraud Against Taxpayers Act, N.M. Stat. Ann. §§ 44-9-1 – 9-14; (24) New York False Claims Act, N.Y. Fin. Law §§ 187 – 194; (25) North Carolina False Claims Act, N.C. Gen. Stat. Ann. §§ 1-605 – 618; (26) Oklahoma Medicaid False Claims Act, Okl. Stat. Ann. tit. 63, §§ 5053 – 5054; (27) Rhode Island State False Claims Act, R.I. Gen. Laws Ann. §§ 9-1.1-1 – 1.1-9; (28) Tennessee False Claims Act, Tenn. Code Ann. §§ 4-18-101 – 108; (29) Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§ 71-5-181 – 185; (30) Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. §§ 36.001 – 36.132; (31) Vermont False Claims Act, Vt. Stat. Ann. tit. 32, §§ 630 – 642; (32) Virginia Fraud Against Tax Payers Act, Va. Code Ann. §§ 8.01-

and restitution owed to the Government as a result of a multi-tiered kickback scheme involving defendants Eli Lilly and Company ("Lilly" or the "Company"); HealthSTAR Clinical Education Solutions LLC ("Healthstar"); VMS BioMarketing ("VMS"); Covance Inc. ("Covance"); and United BioSource Corporation ("UBC"). Collectively, Lilly, VMS, Healthstar, Covance, and UBC are referred to herein as "Defendants."

2. Defendants' unlawful conduct involves Lilly's products (1) Humalog; (2) Humulin; and (3) Forteo. Collectively, Humalog, Humulin, and Forteo are referred to herein as the "Lilly Covered Products."

3. To enrich themselves at the expense of the Government, Lilly, with substantial assistance from Healthstar, VMS, Covance, and UBC, engaged in three intertwined, unlawful marketing schemes for the Lilly Covered Products.

4. First, with assistance from Healthstar and VMS, Lilly provided in-kind remuneration to Prescribers[2] in the form of free nursing services in part to induce them to prescribe the Lilly Covered Products to their patients.

5. Second, Lilly contracted with and paid remuneration to nurse educators in part to recommend the Lilly Covered Products to Prescribers and patients. While purporting to provide independent medical advice and disease-awareness information, the nurse educators were in reality acting as undercover sales representatives ("sales reps") for Lilly, focused on the mission Lilly had retained them to accomplish: refer the Lilly Covered Products to Prescribers and patients.

216.1 – 216.19; and (33) Washington Medicaid Fraud False Claims Act, Wash. Rev. Code Ann. §§ 74.66.005 – 74.66.130.

[2] As used herein, the term "Prescriber" refers to any physician or Advance Practice Provider authorized to write prescriptions, as well as their employers.

6. Third, with assistance from Covance and UBC, Lilly provided in-kind remuneration to Prescribers in the form of reimbursement support services, saving Prescribers thousands of dollars in administrative expenses. These reimbursement support services were provided in part to induce Prescribers to prescribe the Lilly Covered Products to their patients.

7. The federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b (the "AKS"), expressly prohibits any individual or entity from offering, paying, soliciting, or receiving any "remuneration," which includes "any kickback, bribe, or rebate," to "any person to induce such person" to purchase or recommend a drug or service that is covered by Medicare or Medicaid. *Id.* Further, the U.S. Department of Health and Human Services (the "HHS") has repeatedly warned pharmaceutical companies that they should refrain from engaging in marketing or promotional activities that utilize individuals who are involved in the delivery of healthcare or rely on the provision of free services such as billing, nursing, or other staff services.[3]

8. Lilly recognizes the need to comply with the AKS in promoting its drugs to health care professionals. Among other things, Lilly is a member of the Pharmaceutical Research and Manufacturers of America ("PhRMA").[4] The PhRMA is an organization that represents the country's leading biopharmaceutical researchers and biotechnology companies. The PhRMA promulgates the PhRMA Code as "part of an ongoing effort to ensure that biopharmaceutical marketing practices and informational activities comply with the highest ethical and professional

[3] *See, e.g.*, 56 Fed. Reg. 35952-01, 35981 (July 29, 1991); 59 Fed. Reg. 65372-01, 65376 (Dec. 19, 1994).

[4] PhRMA Code on Interactions with Healthcare Professionals, *Signatory Companies*, *available at* http://phrma-docs.phrma.org/sites/default/files/pdf/signatory_companies_code_on_interactions_with_healthcare_professionals.pdf (last accessed, Dec. 20, 2017).

standards."[5] The PhRMA Code states that pharmaceutical companies, like Eli Lilly, should not provide or offer subsidies, support, or practice-related items "to a healthcare professional in exchange for prescribing products or for a commitment to continue prescribing products." In fact, the Code specifically states that "**[n]othing** should be offered or provided in a manner or on conditions that would interfere with the independence of a healthcare professional's prescribing practices."[6]

9. Lilly is not only a member of the PhRMA, but it is also a signatory to the Code and has announced its intention to abide by the Code.[7]

10. Although Lilly and its co-defendants knew that the AKS prohibited them from providing anything of value to providers or from giving kickbacks to promote the Lilly Covered Products, Defendants disregarded the law, choosing instead to put sales growth and profits before their duties to comply with the law and ensure patient safety and integrity in the healthcare marketplace.

11. The AKS ensures that the Government pays only for conflict-free medical care and prescriptions that are provided in the best interests of the patient. A kickback eliminates any

[5] PhRMA, Press Release: *PhRMA Code on Interactions with Healthcare Professionals* (Apr. 30, 2013), *available at* http://www.phrma.org/press-release/phrma-code-on-interactions-with-healthcare-professionals-reaches-new-milestone-with-54th-signatory-company (last accessed, Dec. 20, 2017).

[6] PhRMA, *Code on Interactions with Healthcare Professionals* at 13 (July 2008)(emphasis added), *available at* http://phrma-docs.phrma.org/sites/default/files/pdf/phrma_marketing_code_2008-1.pdf (last accessed, Dec. 20, 2017) (emphasis added).

[7] PhRMA Code on Interactions with Healthcare Professionals, *Signatory Companies*, *available at* http://phrma-docs.phrma.org/sites/default/files/pdf/signatory_companies_code_on_interactions_with_healthcare_professionals.pdf (last accessed, Dec. 20, 2017).

sound basis for such assurance because it taints the prescribing physician's medical decisions with the prescriber's financial interests. "The Government does not get what it bargained for when a defendant is paid by [the Government] for services tainted by a kickback." *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 314 (3d Cir. 2011) (internal quotations omitted).

12. As is demonstrated below, due to Defendants' conduct, tens of thousands of prescriptions for the Lilly Covered Products were not based purely on clinical efficacy or patient-specific information, but rather were tainted by the unlawful, substantial kickbacks Lilly offered Prescribers.

13. Based on Defendants' illegal marketing and promotion schemes, pharmacies have submitted and continue to submit claims to Medicare and Medicaid that were tainted by kickbacks, causing these programs to pay billions of dollars in improper reimbursements.

JURISDICTION AND VENUE

14. This Court has jurisdiction over the Government's claims pursuant to 28 U.S.C. §§ 1331 and 1345.

15. This Court may exercise personal jurisdiction over Lilly, Healthstar, VMS, Covance, and UBC because a substantial part of the acts giving rise to the Government's claims occurred within the State of Texas.

16. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1391(b) and 1391(c) because Lilly, Healthstar, VMS, Covance, and UBC each transact business in this District and/or, in furtherance of its fraudulent kickback schemes, caused to be submitted or conspired to submit false claims in this District.

THE PARTIES

17. Lilly is a publicly-traded pharmaceutical company headquartered in Indianapolis, Indiana. Lilly sells pharmaceuticals throughout the United States.

18. Healthstar is a privately-held corporation headquartered in Mahwah, New Jersey. According to its website, Healthstar provides "a comprehensive portfolio of unique and traditional healthcare marketing services."[8] Among those services are marketing services for the pharmaceutical industry, including the provision of clinical educators. According to Healthstar, one of the goals of clinical educators is to "enhance the sales representatives' access to physicians and create a receptive audience for their message."[9]

19. VMS is a company headquartered in Indianapolis, Indiana. According to its website, VMS offers "Clinical Educators" with "clinical acumen [that] improves access to and credibility with healthcare professionals—which builds brand awareness."[10]

20. Covance is a company headquartered in Princeton, New Jersey. According to its website, Covance offers services such as "[i]dentify[ing] prior authorization requirements to smooth the process for patients and providers."[11] The website also touts Covance's "Market

[8] HealthSTAR Communications, *available at* http://www.healthstarcom.com (last visited May 24, 2017).

[9] HealthSTAR Clinical Education Solutions, *available at* http://www.healthstarces.com/clinical.html (last visited May 24, 2017).

[10] VMS BioMarketing Educator Network Solutions, *available at* https://www.vmsbiomarketing.com/focus/solutions/educator-networks (last visited June 13, 2017).

[11] Covance Patient Access Programs, *available at* http://www.covance.com/industry-solutions/healthcare/commercialization/patient-and-provider-services/patient-access-programs.html (last visited June 13, 2017).

Access Field Team" that provides "on-site assistance to healthcare professionals . . . ."[12] Covance is a subsidiary of Laboratory Corporation of America Holdings, a publicly-traded company headquartered in Burlington, North Carolina.

21. UBC is a company headquartered in Blue Bell, Pennsylvania. According to its website, UBC, among other things, "helps patients and prescribers maneuver the ever changing reimbursement obstacles to product access while improving speed to therapy."[13] UBC is a subsidiary of Express Scripts, Inc. ("ESI") a publicly-traded company headquartered in St. Louis, Missouri.

22. Relator Health Choice Alliance is an affiliate of the National Healthcare Analysis Group ("NHAG"), a research organization based in New Jersey. Each year, NHAG representatives conduct hundreds of interviews of participants in the healthcare marketplace – nurses, sales reps, office managers, administrators, reimbursement support personnel, etc. – to form an understanding of industry practices.

23. Relator brings this action on behalf of the Government pursuant to the *qui tam* provisions of the federal False Claims Act, 31 U.S.C. § 3729 – 3733, and the false claims acts of the respective Plaintiff States.

[12] Id.

[13] UBC Patient Access and Engagement Services, *available at* http://www.ubc.com/services/loyalty/reimbursement-patient-assistance (last visited June 7, 2017).

STATUTORY BACKGROUND

24. In relevant part, the FCA, 31 U.S.C. § 3729(a)(1)(A) – (C), establishes treble damages liability to the United States for any individual or entity that:

> knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> knowingly makes or uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; or
>
> conspires to commit a violation of [the foregoing paragraphs].

Within the meaning of the FCA, "knowingly" is defined to include reckless disregard and deliberate ignorance. 31 U.S.C. § 3729(b)(1). In addition to treble damages, the FCA also provides for assessment of a civil penalty for each violation or each false claim.

25. In relevant part, the AKS, 42 U.S.C. § 1320a-7b, provides as follows:

> (b) Illegal Remunerations.
>
> (1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—
>
> (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.
>
> (2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—

> (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

26. For purposes of the AKS, "remuneration" includes the transfer of anything of value, whether cash or in-kind consideration, directly or indirectly, covertly or overtly. Importantly, the statute has been interpreted to cover any arrangement where one purpose of the remuneration is to obtain money for referral of services or to induce further referrals.

27. The AKS is designed to, among other things, ensure that patient care will not be improperly influenced by inappropriate compensation from the pharmaceutical industry, and that healthcare professionals remain free of conflicts of interest that could impact treatment decisions.

28. To ensure compliance, every federally-funded health care program requires every provider or supplier to ensure compliance with the provisions of the AKS and other federal laws governing the provision of health care services in the United States.

29. The AKS was amended in March 2010 as part of the Patient Protection and Affordable Care Act ("PPACA"), which clarified that "[a]n AKS violation that results in a federal health care payment is a per se false claim under the FCA." *United States ex rel. Lutz v. Bluewave Healthcare Consultants, Inc.*, 853 F.3d 131, 136 (4th Cir. 2017); 42 U.S.C. § 1320a-7b(g). The PPACA also makes clear that violations of its anti-kickback provisions, like violations of the FCA, may occur even if an individual does "not have actual knowledge" or

"specific intent to commit a violation." Pub. L. No. 111-148, 124 STAT. 759 § 6402 (adding new section, § 1128J(h)).

30. The courts have recognized that claims for reimbursement for medical care tainted by illegal kickbacks are "false" claims within the meaning of the FCA. *See, e.g., United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 315 (3d Cir. 2011); *United States ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377, 392-93 (1st Cir. 2011).

31. Knowingly providing kickbacks to Prescribers to induce them to prescribe a drug (or to influence prescriptions) to individuals who seek reimbursement for the drug from a federal Government healthcare program or causing others to do so, while certifying compliance with the AKS (or while causing another to so certify), or billing the Government as if in compliance with these laws, violates the FCA.

32. A violation of the AKS constitutes a felony. Any party convicted under the AKS must be excluded from federal health care programs for a term of at least five years. 42 U.S.C. § 1320a-7(a).

33. Compliance with the AKS is required for reimbursement of claims from federal health care programs, and claims made in violation of the law are actionable civilly under the FCA. 42 U.S.C. § 1320a-7b(g) (stating, in part, that "a claim that includes items or services resulting from a violation of . . . [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]"); *see also United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 313 (3d Cir. 2011) (stating that "[c]ompliance with the AKS is clearly a condition of payment under Parts C and D of Medicare"). Compliance with the AKS is thus a fundamental and material aspect of what the government purchases when it pays for medical care for federally insured beneficiaries.

34. The AKS contains statutory exceptions and certain regulatory "safe harbors" that exclude certain types of conduct from the reach of the statute. *See* 42 U.S.C. § 1320a-7b(b)(3). None of the statutory exceptions or regulatory safe harbors protect Defendants from liability for the conduct alleged herein.

35. Each of the Plaintiff States has enacted statutes that are parallel to the legislative scheme embodied in the FCA and the AKS.

AFFECTED HEALTH PROGRAMS

36. Generally, when a Prescriber prescribes one of the Lilly Covered Products, a patient is provided with a prescription that is then filled at a pharmacy. The pharmacy then submits the claim for payment to the relevant federal health care program(s) for reimbursement.

37. In certain circumstances, a federal program may also have pharmacy facilities that directly dispense prescription drugs. In such cases, the federal health care program purchases the drug directly rather than reimbursing the pharmacy.

Medicare

38. Medicare is a federal program that provides federally-subsidized health insurance primarily for persons who are 65 or older or are disabled. *See* 42 U.S.C. §§ 1395 *et seq.* ("Medicare Program").

39. Part D of the Medicare Program was enacted as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, to provide prescription drug benefits for Medicare beneficiaries. Medicare Part D became effective January 1, 2006.

40. All persons enrolled in Medicare Part A or Medicare Part B are eligible to enroll in a prescription drug plan under Part D. HHS, through its component agency, the Center for

Medicare and Medicaid Services ("CMS"), contracts with private companies (or "Part D sponsors") to administer prescription drug plans. Such companies are regulated and subsidized by CMS pursuant to one-year, annually renewable contracts. Part D sponsors enter into subcontracts with many pharmacies to provide drugs to the Medicare Part D beneficiaries enrolled in their plans.

41. Generally, after a Prescriber writes a prescription for a patient who is a Medicare beneficiary, that patient can take the prescription to a pharmacy to be filled. When the pharmacy dispenses drugs to the Medicare beneficiary, the pharmacy submits a claim electronically to the beneficiary's Part D sponsor (sometimes through the sponsor's pharmacy benefit manager, or "PBM"). The pharmacy receives reimbursement from the sponsor (or PBM) for the portion of the drug cost not paid by the beneficiary. The Part D sponsor is then required to submit to the CMS an electronic notification of the drug dispensing event, called the Prescription Drug Event ("PDE"), which contains data regarding the prescription claim, including the service provider of the drug, the prescriber of the drug, the quantity dispensed, the amount paid to the pharmacy, and whether the drug is covered under the Medicare Part D benefit.

42. Payments to a Part D Plan sponsor are "conditioned upon the provision of information to CMS that is necessary" for CMS to administer the Part D program and make payments to the Part D Plan sponsor for qualified drug coverage. 42 C.F.R. § 423.322. CMS's instructions for the submission of Part D prescription PDE claims data state that "information . . . necessary to carry out this subpart" includes the data elements of a PDE. PDE records are an integral part of the process that enables CMS to administer the Part D benefit. Each PDE that is submitted to CMS is a summary record that documents the final adjudication of a dispensing event based upon claims received from pharmacies and serves as the request for payment for

each individual prescription submitted to Medicare under the Part D program.

43. CMS gives each Part D sponsor advance monthly payments consisting of the Part D sponsor's plan's direct subsidy per enrollee (which is based on a standardized bid made by the Part D sponsor), estimated reinsurance subsidies for catastrophic coverage, and estimated low income subsidies. 42 C.F.R. §§ 423.315, 423.329. At the end of the payment year, CMS reconciles the advance payments paid to each Part D sponsor with the actual costs the sponsor has incurred. In this reconciliation process, CMS uses the PDE claims data it has received from the Part D sponsor during the prior payment year to calculate the costs the Part D sponsor has actually incurred for prescriptions filled by Medicare beneficiaries under Part D. If CMS underpaid the sponsor for low-income subsidies or reinsurance costs, it will make up the difference. If CMS overpaid the sponsor for low-income subsidies or reinsurance costs, it will recoup the overpayment from the sponsor. After CMS reconciles a plan's low-income subsidy and reinsurance costs, it then determines risk-sharing amounts owed by the plan to CMS or by CMS to the plan related to the plan's direct subsidy bid. Risk-sharing amounts involve calculations based on whether and to what degree a plan's allowable costs exceeded or fell below a target amount for the plan by certain threshold percentages. 42 C.F.R. § 423.336.

44. CMS's payments to the Part D sponsor come from the Medicare Prescription Drug Account, an account within the Federal Supplementary Medical Insurance Trust Fund. 42 C.F.R. § 423.315(a).

45. To receive Part D funds from CMS, Part D Plan sponsors, as well as their authorized agents, employees, and contractors (including pharmacies), are required to comply with all applicable federal laws, regulations, and CMS instructions.

46. By statute, all contracts between a Part D Plan sponsor and the HHS must include

a provision whereby the Plan sponsor agrees to comply with the applicable requirements and standards of the Part D program as well as the terms and conditions of payment governing the Part D program. 42 U.S.C. § 1395w-112(b)(1).

47. Medicare Part D Plan sponsors must also certify in their contracts with CMS that they agree to comply with all federal laws and regulations designed to prevent fraud, waste, and abuse, including the FCA and AKS. 42 C.F.R. § 423.505(h)(l).

48. In accordance with these express statutory and regulatory requirements, all contracts entered into between CMS and Plan D Plan sponsors from 2006 through the present include a provision in which the sponsor "agrees to comply with . . . Federal laws and regulations designed to prevent fraud, waste, and abuse, including, but not limited to, applicable provisions of Federal criminal law, the False Claims Act (31 U.S.C. §§ 3729 *et seq.*), and the Anti-Kickback Statute (section 1128B(b) of the Act)." 42 C.F.R. § 423.505(h)(1).

49. CMS regulations further require that all subcontracts between Part D Plan sponsors and downstream entities (such as pharmacies and PBMs) contain language obligating the entities in question to comply with all applicable federal laws, regulations, and CMS instructions. 42 C.F.R. § 423.505(i)(4)(iv).

50. A Part D Plan sponsor also is required to certify to the accuracy, completeness and truthfulness of the PDE claims data submitted to CMS. Specifically, the relevant regulatory provision, entitled "Certification of data that determine payment," provides in relevant part:

> (1) General rule. As a condition for receiving a monthly payment under subpart G of this part (or for fallback entities, payment under subpart Q of this part), the Part D plan sponsor agrees that its chief executive officer (CEO), chief financial officer (CFO), or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must request payment under the contract on a document that certifies (based on best knowledge, information, and belief)

> the accuracy, completeness, and truthfulness of all data related to payment. The data may include specified enrollment information, claims data, bid submission data, and other data that CMS specifies.
>
> (2) Certification of enrollment and payment information. The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that each enrollee for whom the organization is requesting payment is validly enrolled in a program offered by the organization and the information CMS relies on in determining payment is accurate, complete, and truthful and acknowledge that this information will be used for the purposes of obtaining Federal reimbursement.
>
> (3) Certification of claims data. The CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the claims data it submits under § 423.329(b)(3) (or for fallback entities, under § 423.87l(f)) are accurate, complete, and truthful and acknowledge that the claims data will be used for the purpose of obtaining Federal reimbursement.

42 C.F.R. § 423.505(k).

51. Compliance with the regulatory requirement that the PDE data submitted to CMS be true, accurate, and complete is a condition of payment under the Medicare Part D program. *See id.* at 423.505(k)(1).

52. In accordance with this regulatory requirement, since the Part D program began, Medicare required each Part D Plan sponsor to sign annually an Attestation of Data Relating to CMS Payment to a Medicare Part D Sponsor ("Attestation"). This Attestation states:

> Pursuant to the contract(s) between the Centers for Medicare & Medicaid Services (CMS) and the Medicare Part D Organization(s) listed above, hereafter referred to as the Part D Organization, governing the operation of the contract numbers listed above, the Part D Organization hereby makes the following attestations concerning CMS payments to the Part D Organization:
>
> The Part D Organization attests that based on its best knowledge, information, and belief, the final Prescription Drug Event (PDE) data that have been submitted to and accepted by CMS as of [date] with respect to

> the Part D plans offered under the above-stated contract(s) for the dates of service of January 1, [prior year] to December 31, [prior year], are accurate, complete, and truthful and reflect all retroactive adjustments of which the Part D organization has been informed by May 30, [current year]. In addition, the Part D Organization attests that based on best knowledge, information, and belief, the payments that have been made by the Part D organization for the claims summarized by the aforementioned PDE data were made in accordance with the coordination of benefits guidance in Chapter 14 of the Medicare Prescription Drug Benefit Manual and other applicable CMS guidance. The Part D Organization attests that based on its best knowledge, information, and belief as of the date(s) of last successful DIR [Direct and Indirect Remuneration Data] [prior year] data submission(s) via the Health Plan Management System (HPMS) as listed above, the final direct and indirect remuneration data submitted to CMS for the Part D plans offered under the above-stated contract(s) for the [prior] coverage year are accurate, complete, and truthful and fully conform to the requirements in the Medicare Part D program regulations and the Final Medicare Part D DIR Reporting Requirements for [the prior year]. The Part D Organization also certifies that based on its best knowledge, information, and belief as of the date indicated below, all other required information provided to CMS to support the determination of allowable reinsurance and risk corridor costs for the Part D plans offered under the above-stated contract(s) is accurate, complete, and truthful. With regards to the information described in the above paragraphs, the Part D Organization attests that it has required all entities, contractors, or subcontractors, which have generated or submitted said information (PDE and DIR data) on the Part D Organization's behalf, to certify that this information is accurate, complete, and truthful based on its best knowledge, information, and belief. In addition, the Part D Organization attests that it will maintain records and documentation supporting said information. The Part D Organization acknowledges that the information described in the above paragraphs will be used for the purposes of obtaining federal reimbursement and that misrepresentations or omissions in information provided to CMS may result in Federal civil action and/or criminal prosecution.

53. All approved Part D Plan sponsors who received payment under Medicare Part D in benefit years 2006 through the present date submitted these required Attestations in the same or similar format.

54. Medicare regulations further provide: "If the claims data are generated by a related entity, contractor, or subcontractor of a Part D plan sponsor, the entity, contractor, or

subcontractor must similarly certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the data and acknowledge that the claims data will be used for the purposes of obtaining Federal reimbursement." 42 C.F.R. § 423.505(k)(3).

55. Medicare also enters into agreements with physicians to establish the physician's eligibility to participate in the Medicare program. To be eligible for participation in the Medicare program, physicians must certify that they agree to comply with the Anti-Kickback Statute, among other federal health care laws. Specifically, on the Medicare enrollment form, CMS Form 855I, the "Certification Statement" that the medical provider signs states: "You MUST sign and date the certification statement below in order to be enrolled in the Medicare program. In doing so, you are attesting to meeting and maintaining the Medicare requirements stated below." Those requirements include:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to me . . . . The Medicare laws, regulations and program instructions are available through the fee-for-service contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier's compliance with all applicable conditions of participation in Medicare.
>
> I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity.

56. Lastly, when submitting a claim using the CMS claim form, the provider certifies that the claim, whether submitted by the provider or on the provider's behalf, "complies with all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment including but not limited to the Federal anti-kickback statute . . . ." Moreover, the provider certifies that the services claimed on the form "were medically necessary and personally furnished by [the provider] or were furnished incident to [the provider's] professional service. . .

."[14]

Medicaid

57. Medicaid is a joint federal-state program created in 1965 that provides health care benefits for certain groups, primarily the poor and disabled. Each state administers a State Medicaid program.

58. The federal Medicaid statute requires each participating state to implement a plan containing certain specified minimum criteria for coverage and payment of claims. 42 U.S.C. §§ 1396, 1396a(a)(13), 1396a(a)(30)(A). While drug coverage is an optional benefit, the Medicaid programs of all states provide reimbursement for prescription drugs.

59. The federal portion of each state's Medicaid payments, known as the Federal Medical Assistance Percentage ("FMAP"), is based on the state's per capita income compared to the national average. 42 U.S.C. § 1396d(b). Federal funding under Medicaid is provided only when there is a corresponding state expenditure for a covered Medicaid service to a Medicaid recipient. The federal government pays to the state the statutorily established share of the "total amount expended . . . as medical assistance under the State plan." 42 U.S.C. § 1396b(a)(l).

60. The vast majority of states award contracts to private companies to evaluate and process claims for payment on behalf of Medicaid recipients. Typically, after processing the claims, these private companies generate funding requests to the state Medicaid programs.

61. Before the beginning of each calendar quarter, each state submits to CMS an estimate of its Medicaid federal funding needs for the quarter. CMS reviews and adjusts the quarterly estimate as necessary, and determines the amount of federal funding each state will be

[14] Centers for Medicare & Medicaid Services, CMS 1500 – Health Insurance Claim Form, *available at* https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS1500.pdf (last accessed, Dec. 20, 2017).

permitted to draw down as it incurs expenditures during the quarter. The state then draws down federal funding as actual provider claims, including claims from pharmacies seeking payment for drugs, are presented for payment. After the end of each quarter, the state submits to CMS a final expenditure report, which provides the basis for adjustment to the quarterly federal funding amount (to reconcile the estimated expenditures to actual expenditures). 42 C.F.R. § 430.30.

62. Claims arising from illegal kickbacks are not authorized to be paid under state regulatory regimes. In fact, providers who participate in the Medicaid program must sign enrollment agreements with their states that certify compliance with the state and federal Medicaid requirements, including the AKS. Although there are variations among the states, the agreement typically requires the prospective Medicaid provider to agree that he or she will comply with all state and federal laws and Medicaid regulations in billing the state Medicaid program for services or supplies furnished.

63. Furthermore, in many states, Medicaid providers, including both physicians and pharmacies, must affirmatively certify compliance with applicable federal and state laws and regulations.

64. For example, in New York, physicians and pharmacies must periodically sign a "Certification Statement for Provider Billing Medicaid," in which the provider certifies that claims submitted "to the State's Medicaid fiscal agent, for services or supplies furnished, [. . .] will be subject to the following certification . . . . I (or the entity) have furnished or caused to be furnished the care, services, and supplies itemized and done so in accordance with applicable federal and state laws and regulations."

65. Similarly, in Texas, "providers (and submitters on behalf of providers) must affirm that they have read, understood, and agree to the certification and terms and conditions of

the prior authorization request" before submitting each prior authorization request. By agreeing, the provider and authorization request submitter certify that the information supplied concerning the prior authorization "constitute true, correct, and complete information." Further, the provider and authorization request submitter "understand that payment of claims related to this prior authorization will be from federal and state funds, and that falsifying entries, concealment of a material fact, or pertinent omissions may constitute fraud and may be prosecuted under applicable federal and/or state law." The consequences of omitting information or failing to provide true and accurate information are "termination of the provider's Medicaid enrollment and/or personal exclusion from Texas Medicaid."[15]

66. Additionally, "Texas Medicaid service providers are required to certify compliance with or agree to various provisions of state and federal laws and regulations."[16]

TRICARE

67. TRICARE is part of the United States military's health care system, designed to maintain the health of active duty service personnel, provide health care during military operations, and offer health care to non-active duty beneficiaries, including dependents of active duty personnel, and military retirees and their dependents. The military health system, which is administered by the Department of Defense ("DOD"), is composed of the direct care system, consisting of military hospitals and military clinics, and the benefit program, known as

[15] Texas Medicaid Provider Procedures Manual § § 5.5.1.2.1 – 5.5.1.2.3 (Dec. 2017), *available at* http://www.tmhp.com/Pages/Medicaid/Medicaid_Publications_Provider_manual.aspx (last accessed, Dec. 20, 2017).

[16] Texas Medicaid Provider Procedures Manual § 1.6.8 (Dec. 2017) (emphasis in original), *available at* http://www.tmhp.com/Pages/Medicaid/Medicaid_Publications_Provider_manual.aspx (last accessed, Dec. 20, 2017).

TRICARE. TRICARE is a triple-option benefit program designed to give beneficiaries a choice between health maintenance organizations, preferred provider organizations, and fee-for-service benefits.

68. TRICARE prescription drug benefits are provided through three different programs: military treatment facility outpatient pharmacies, TRICARE network retail pharmacies, and TRICARE's mail order service. TRICARE contracts with a PBM to administer its retail and mail order pharmacy programs. In addition, TRICARE beneficiaries can also pay out-of-pocket to fill prescriptions at non-network retail pharmacies, and submit a claim for reimbursement directly with TRICARE's PBM. The claims process is different for each of these pharmaceutical programs.

69. When a TRICARE beneficiary brings a prescription to a TRICARE network retail pharmacy, for example, the pharmacy submits an electronic claim to the PBM for that prescription event. The PBM sends an electronic response to the pharmacy that confirms the beneficiary's TRICARE coverage, and, if the prescription claim is granted, informs the pharmacy of the calculated pharmacy reimbursement amount and the co-pay (if applicable) to be collected from the beneficiary. The pharmacy then collects the co-pay amount (if any) from the beneficiary and dispenses the medication. After a 10-day hold to ensure the prescription was picked up and not returned to the shelf by the pharmacy, the PBM sends a TRICARE Encounter Data ("TED") record electronically to TRICARE. The TED record includes information regarding the prescription event, including the reimbursement amount to be paid to the dispensing pharmacy. TRICARE then authorizes the PBM to make payment to the pharmacy for the amount remaining (after co-pay) on the claim. The PBM sends the payment to the pharmacy. After the payment is made by the PBM's bank, the PBM's bank requests reimbursement from

the Federal Reserve Bank ("FRB"). The FRB then transfers funds to the PBM's bank account.

70. If the prescription is filled at a non-network retail pharmacy, the beneficiary must pay the full price of the prescription to the pharmacist and file a claim for reimbursement on DD Form 2642, TRICARE/DOD.CHAMPUS Medical Claim- Patient's Request for Medical Payment ("Form 2642"). The Form 2642 is mailed to the PBM. As in the case of reimbursements under the retail pharmacy program, a TED record is created and sent to TRICARE. TRICARE then authorizes payment to the TRICARE beneficiary. Upon receiving that authorization, the PBM issues a check to the beneficiary, which is drawn on the PBM's bank account. TRICARE then reimburses the PBM in the same manner as it does under the retail pharmacy program, such that funds are transferred from the FRB to the PBM's bank account.

71. TRICARE beneficiaries can also fill prescriptions through TRICARE's mail order pharmacy program. TRICARE beneficiaries submit prescriptions by mail, fax, or electronically to TRICARE's PBM, along with any co-pay (if applicable). TRICARE's PBM delivers the prescription to the beneficiary via free standard shipping. The medications dispensed through the mail order pharmacy program are filled from the PBM's existing inventory of pharmaceuticals. The PBM then requests replenishment pharmaceuticals from DOD's national prime vendor contracted by the Defense Logistics Agency ("DLA"). DOD procures the pharmaceuticals through its national prime vendor and replenishes the PBM's inventory of pharmaceuticals. The PBM then submits a TED record to TRICARE to obtain administrative fees. DLA bills TRICARE directly for drug replenishment costs.

72. Pursuant to 38 U.S.C. § 8126, pharmaceutical manufacturers are required to enter into national contracts with the DOD pursuant to which the manufacturer makes available for procurement certain covered drugs at the Federal Ceiling Price (a price that is calculated as at

least 24% less than the manufacturer's average price based on all sales to commercial customers through a wholesaler or distributor). Pursuant to DOD's contract with its national prime vendor, the national prime vendor submits an invoice to the DOD for payment of pharmaceuticals supplied to the PBM in connection with the mail order pharmacy program, charging the DOD the price set by the contract awarded by the DOD to the drug manufacturer.

73. Since March 2003, TRICARE has contracted ESI to administer TRICARE's mail order pharmacy programs. ESI has also administered TRICARE's retail pharmacy program since June 2004.

74. Similarly, TRICARE's military treatment facilities purchase medications through procurement contracts with third party pharmaceutical prime vendors. When a TRICARE beneficiary submits an outpatient prescription to a military treatment facility's outpatient pharmacy, the pharmacy purchases the medication from the prime vendor pursuant to an existing procurement contract, and the drug is then dispensed to the patient.

75. While some physicians enroll in the TRICARE program as network or participating providers, any physician that is licensed, accredited and meets other standards of the medical community is authorized to provide services to TRICARE beneficiaries. Physicians who are enrolled in the TRICARE network must expressly certify their compliance with TRICARE's regulations. Yet all providers that provide services to TRICARE beneficiaries, whether network providers or non-participating providers, are required to comply with TRICARE's program requirements, including its anti-abuse provisions. 32 C.F.R. § 199.9(a)(4). TRICARE regulations provide that claims submitted in violation of TRICARE's anti-abuse provisions can be denied. *Id.* § 199.9(b). Kickback arrangements are included within the definition of abusive situations that constitute program fraud. *Id.* § 199.9(c)(12).

Veterans Administration Health Care

76. The Department of Veteran Affairs ("VA") maintains a system of medical facilities from which all pharmaceutical supplies, including prescription drugs, are procured directly by the VA. A VA beneficiary can take a prescription to a VA medical facility, at which point the VA dispenses the medication to the VA beneficiary from its existing inventory. The VA also supports a mail service prescription program as part of its outpatient drug benefit. VA beneficiaries can submit prescriptions to that mail service program, and the VA then dispenses pharmaceuticals purchased by the VA directly to VA beneficiaries. The VA medical system serves approximately four million veterans.

77. The VA purchases the pharmaceuticals that it dispenses at its medical facilities and through its mail service prescription program through its Federal Supply Schedule ("FSS") program. Pursuant to Public Law 102-585, pharmaceutical manufacturers are required to enter into national contracts with the VA pursuant to which the manufacturer makes available for procurement certain covered drugs at the Federal Ceiling Price. A VA facility that requires a supply of a particular medication (including a mail order facility) submits a purchase order to the VA's pharmaceutical prime vendor for distribution of pharmaceuticals.

78. Pursuant to the PPACA, among other things, all claims to Government reimbursed programs resulting from a violation of the AKS are also a violation of the FCA.

79. Moreover, the statutes and regulations set forth above concerning Medicare, Medicaid, TRICARE, and Veterans Administration Health Care, when viewed together, state that healthcare providers must comply with the AKS in order for claims they cause to be submitted to these programs to be reimbursed.

80. Here, the claims submitted for the Lilly Covered Products violated the AKS

because they stemmed from prescriptions that were tainted by kickbacks, while the participants in the scheme knew that claims for reimbursement would be submitted to the above programs. As such, and as more fully discussed below, the prescribing healthcare providers expressly and impliedly falsely certified compliance with the conditions of payment for, at least, Medicare, Medicaid, TRICARE, and Veterans Administration Health Care.

81. In addition to falsely certifying compliance with the AKS, the healthcare providers also falsely certified compliance with contractual provisions that were conditions for payment.

RELATOR'S INVESTIGATION

82. To unmask Defendants' unlawful conduct, Relator and its representatives interviewed numerous individuals with knowledge of the scheme.

- Confidential Interviewee #1 ("CI-1") was an independent contractor nurse educator for Humalog from 2005 until 2013. Her territory was the southern New Jersey area.
- Confidential Interviewee #2 ("CI-2") was an independent contractor nurse educator for Humalog from 2001 until 2015. Her territory included Tampa, Florida and the surrounding area.
- Confidential Interviewee #3 ("CI-3"), was a diabetes drug rep for Lilly from 2007 until 2016. His territory was the State of California.
- Confidential Interviewee #4 ("CI-4") is employed by Healthstar as a nurse educator Manager for Forteo. She has been there since 2015. Her territory is California, Hawaii, and Nevada.
- Confidential Interviewee #5 ("CI-5") was employed by Healthstar as a

nurse educator for Forteo from 2005 until 2014. Her territory was the State of Tennessee.

- Confidential Interviewee #6 ("CI-6") was employed by Lilly as a Forteo drug rep from 2003 until 2013. His territory was the State of Ohio.
- Confidential Interviewee #7 ("CI-7") was employed by Covance as a Forteo field reimbursement representative from 2015 until 2016. His territory was the State of West Virginia and the surrounding area.

THE FRAUDULENT SCHEMES

83. Based on Relator's investigation, there is overwhelming evidence that Lilly, with substantial assistance from Healthstar, VMS, Covance, and UBC, engaged in a complex, multi-part scheme that involved the payment of kickbacks to Prescribers for the purpose of increasing prescriptions for the Lilly Covered Products.

84. In the first scheme, with assistance from Healthstar and VMS, Lilly provided free nurse services to Prescribers in part to induce them to recommend the Lilly Covered Products to their patients, thereby blurring the lines between independent medical advice and sales.

85. In the second scheme, Lilly contracted with and paid remuneration to nurse educators (hired as independent contractors, or by Healthstar or VMS) in part to recommend the Lilly Covered Products to Prescribers and patients.

86. In the third scheme, with assistance from Covance and UBC, Lilly provided in-kind remuneration in the form of reimbursement support services, saving Prescribers thousands of dollars in administrative expenses, in part to induce Prescribers to recommend Lilly Covered Products.

Scheme One: Free Nurse Services

87. Since at least 2007, Lilly has offered free nurse education and patient management services to induce Prescribers to recommend the Lilly Covered Products. Lilly provided these support services through independently-contracted nurse educators, as well as nurses provided to Lilly by Healthstar and VMS.

88. Most Prescribers typically allocate between 10 to 15 minutes to see routine patients. However, patients suffering from osteoporosis and diabetes oftentimes require extra office time, training, and resources to manage their disease. For this purpose, to treat osteoporosis and diabetes patients, Prescribers oftentimes rely on certified nurse educators. The cost associated with the use of nurse educators, however, is significant – a nurse educator often commands an annual salary that exceeds $60,000, or an average hourly wage of $40.00 per hour.

89. Seeking to exploit the needs of Prescribers and healthcare organizations and the challenges they face in managing patients affected by chronic diseases, Lilly developed a marketing strategy that involved furnishing nurse educators to Prescribers to induce them to prescribe the Lilly Covered Products.

90. According to CI-1, Lilly's diabetes nurse educator program – the "Diabetes Interactive Network" – involves at least 500 nurse educators. According to CI-4, Lilly's osteoporosis nurse educator program – "Forteo Connect" – involves approximately 270 nurse educators. Both programs have been around since at least 2007.

91. The Confidential Interviewees confirmed that Lilly's drug reps and nurse educators were trained by Lilly to encourage Prescribers to off-load their patients to the nurse educators for management. CI-2 stated that "the company agenda" was to get Prescribers to utilize the nurse educator services.

92. Lilly's Diabetes nurse educator patient trainings were most often held in group sessions and were usually conducted in the Prescribers' office. The trainings lasted about an hour included training regarding diet, exercise, and administration of Lilly diabetes drugs, including Humalog and Humulin. Interviewees confirmed that patients could attend as many nurse educator training sessions as they wanted.

93. Lilly's Forteo Connect nurse educator patient trainings were generally one-on-one sessions and were typically conducted in the patient's home. The trainings lasted about an hour and included information on how to inject Forteo. Interviewees confirm that each patient that was prescribed Forteo received at least one training by a nurse educator, but the patient could request as many training sessions as they wanted.

94. The nurse educator programs provided valuable, tangible, benefits to Prescribers. As CI-1, a nurse educator, explained: "[Prescribers] know that they can write the prescription and not have to worry about the additional time spent in the office for training from either the staff or themselves. We did follow-up phone calls. We would report back to their offices. So there was that ease of being able to have more patients on the right therapy because there was the additional support [of nurse educators] to the office." CI-1 further explained that she believed the greatest benefit to Prescribers "was just the additional time and the serving [of] the relationship with their patients." This translated to an additional benefit of patient retention because "patients would trust their providers more in providing for the therapy."

95. Along the same lines, CI-4, a nurse educator, explained that her services saved Prescribers time and money because "if the doctors spent the time [nurse educators] spend educating, they'd be out of business."

96. Interviewees further acknowledged that there was a *direct* relationship between

Lilly's nurse educators and prescriptions for Lilly Covered Products. As CI-2 explained, Prescribers would "prescribe [Lilly Covered Products] so their patients can get this additional education because this additional education helps [their patients] to be better self-managers." CI-2 taught patients "[s]elf-management of their disease state without sacrificing any time from the doctors to see any other patients or [any time from] their schedule, and at no cost."

97. In sum, in return for prescribing the Lilly Covered Products to patients, Prescribers reduced the time and cost required to treat those patients, freed up time to see other patients, and increased profitability. The nurse educators were effectively free employees given to Prescribers in exchange for the Prescribers' commitment to recommend the Lilly Covered Products over competing products. Lilly's nurse educators enabled Prescribers to "eliminate an expense that [they] would have otherwise incurred."[17] Lilly's "Free Nurse" marketing scheme thus violates the AKS.

Scheme Two: White Coat Marketing by Nurse Educators

98. Since at least 2007, with assistance from Healthstar and VMS, Lilly has relied on nurse educators to help promote the Lilly Covered Products, obtain better access to Prescribers, and influence Prescribers to prescribe the Lilly Covered Products.

99. Prescribers often restrict or deny access to drug reps, but tend to be more willing to meet with healthcare professionals. Accordingly, Lilly resorted to nurse educators to gain access to Prescribers and promote the Lilly Covered Products.

[17] *OIG* Compliance Program Guidance for Pharmaceutical Manufacturers, Dep't of Health & Human Servs., 68 Fed. Reg. 23731-01, 23737 (May 5, 2003), *available at* https://oig.hhs.gov/fraud/docs/complianceguidance/042803pharmacymfgnonfr.pdf (if "services provided by the manufacturer eliminate an expense that the physician would have otherwise incurred (*i.e.,* have independent value to the physician) . . . the arrangement may be problematic if the arrangement is tied directly or indirectly to the generation of federal health care program business for the manufacturer").

100. Lilly's relationship with the nurse educators and Healthstar and VMS plainly involves the payment of a kickback – cash consideration – in return for services that ultimately led to prescriptions being filled and paid for with Government money.

101. In this case, Lilly paid remuneration to nurse educators to recommend the Lilly Covered Products over competing products to Prescribers and patients. The nurses were likely to be viewed by Prescribers as better credentialed and more credible than traditional drug reps, and, thus, they were more likely to gain access to Prescribers and their staff.

102. The Office of Inspector General ("OIG") refers to the practice of utilizing healthcare providers, like nurses, to promote particular drugs as "white coat marketing," and has warned against the practice.

> The fraud and abuse risks are compounded where . . . a physician or other health care professional is involved in the marketing activity—a practice sometimes referred to as "white coat" marketing. White coat marketing is closely scrutinized under the anti-kickback statute because physicians and other health care professionals are in an exceptional position of public trust and thus may exert undue influence when recommending health care-related items or services . . . .[18]

103. Lilly paid nurse educators directly, and paid Healthstar, and VMS to hire nurse educators, to recommend the Lilly Covered Products to doctors and patients and drive sales.

104. Lilly, Healthstar, and VMS needed a clever approach to disguise this marketing strategy. After all, the nurse educators could not openly play the role of drug reps for at least three reasons. First, Prescribers would potentially limit nurse access, in the same manner that drug rep access was being limited. Second, if Prescribers knew that the nurses were nothing more than sales reps in disguise, Prescribers would discount the nurses' "recommendations" as

[18] *See, e.g.*, OIG Op. 11-08, at 6 (Jun. 14, 2011), *available at* https://oig.hhs.gov/fraud/docs/advisoryopinions/2011/AdvOpn11-08.pdf.

biased. Third, the OIG has identified white coat marketing as particularly suspect and the AKS prohibits pharmaceutical companies from paying non-employees to "recommend" its drugs to others.[19] Since the nurses involved in this scheme were not Lilly employees, Lilly, Healthstar, and VMS could not openly pay the nurses to exclusively recommend Lilly Covered Products.

105. In an attempt to circumvent the law, Lilly contrived a disease awareness program that would act as a cover for the nurses, seemingly distinguishing them from drug reps and enabling them to appear to be independent. Lilly, Healthstar, and VMS designated the nurses as "educators" who, instead of being paid to recommend drugs, were purportedly there to promote free educational services to Prescribers.

106. Although the nurses were independent contractors and were purportedly "educators," they were expected to and did recommend Lilly Covered Products. This conclusion is compelled by numerous facts Relator uncovered during its investigation.

107. ***The nurse "educators" received sales training***. Lilly invested heavily in training nurse educators how to gain access to Prescribers and promote Lilly Covered Products. This training was a *vital* component of the scheme because Lilly's ultimate goal was to drive drug sales.

108. CI-2, a nurse educator, acknowledged that she was trained on "the way a product is marketed and the way you deliver a message. They give you training on those things." CI-2 stated that through her training she "understand[s] these products and general objections and can speak easily as to whatever barriers providers may have in prescribing a product."

109. Both CI-1 and CI-2's training consisted of role playing and overcoming Prescriber objections. Particularly, CI-1 said that when she was being taught how to overcome

[19] 42 U.S.C. § 1320a-7b(b).

Prescriber and staff objections, she did "a lot of situational-based type of training. [Such as,] dealing with the rejection of going into an office. They would just talk us through the different ways to deal: when to leave the office, when to return back to see if they had a change of heart . . . ."

110. Further, CI-2 explained that she was trained only on the information that Lilly believed to be material to sales. CI-2 noted that educators "didn't need a blanket education of all products available for diabetes management. So, if you're teaching on a product, they gave us information and showed us research that helped us understand the validity *of the product that they're asking us to teach about*."

111. ***The nurse "educators" were actively used by Lilly to drive sales.*** Once trained, Lilly selectively deployed nurse educators to target Prescribers and facilities with high potential to prescribe the Lilly Covered Products. To maximize the chances of success, the nurse educators coordinated with Lilly drug reps and would oftentimes accompany them on sales calls.

112. CI-1 explained that the offices she was deployed to were "specifically [ ] targeted based upon the writing habits already of the provider."

113. Lilly also used the nurse educators to approach Prescribers that were resistant to sales calls. As CI-2, a nurse educator, explained, when Lilly's sales reps ran into difficult Prescribers, Lilly would "get a nurse educator to speak to them. You go in with an advantage. The provider doesn't want to talk to a drug rep, you're not a drug rep so bada bing bada boom."

114. CI-3, a drug rep, similarly indicated that nurse educators were able to gain access to certain Prescribers in circumstances where drug reps would not be able to because "the drug reps are a dime a dozen. So if the doctors feel there might be [a] little more educational value for their patients or staff, they are much more willing to open their doors for actual diabetes

educators as opposed to drug reps."

115. ***The nurse educators were tasked with promoting Lilly products.*** The mission of the nurse educators was to increase prescriptions of Lilly products. As CI-1 explained, "[W]hen you are going in you are being paid by Eli Lilly to conduct the program on Humalog products . . . . So you are not going to [go] in and talk about starting your patient first on Metformin, when you are speaking for [Lilly], because [Metformin] is part of another drug." CI-1 similarly indicated that nurse educators "*are promoting [Lilly] product[s] because we are being paid by that company* [Lilly]." Along the same lines, CI-3, a drug rep, indicated that "*contractually* [nurse educators] are there to promote Humalog . . . ."

116. In sum, Lilly's nurse educator programs were nothing more than a scheme to drive prescriptions for the Lilly Covered Products. By providing remuneration, directly and via Healthstar and VMS, to employ and deploy "white coated" nurses to recommend the Lilly Covered Products, the Defendants violated the AKS. The AKS proscribes the conduct, *i.e.*, payment or offer of payment to "any person" in exchange for a recommendation or referral. It is immaterial if the payee receiving the remuneration in exchange for recommending a drug is a doctor (who can recommend by writing a patient a prescription) or some other payee, such as a nurse, a medical assistant, a patient recruiter, or a runner, who can recommend the drug to a patient or a Provider. By compensating nurses in part to recommend the Lilly Covered Products, Lilly violated the AKS.

Scheme Three: Reimbursement Support Services

117. To induce recommendations of the Lilly Covered Products over competing products, Lilly sales reps also offered a third type of kickback: free reimbursement support services for Prescribers who wrote prescriptions for the Lilly Covered Products.

118. This remuneration was a tangible, in-kind benefit that greatly reduced, and in some instances eliminated, Prescribers' administrative costs related to prescribing Lilly Covered Products. Lilly referred to this remuneration as coverage determination and/or reimbursement support services, but in practice, the services were intended to induce Prescribers to choose Lilly Covered Products over a competitor's products.

119. With the assistance of Covance and UBC, Lilly hired and trained dozens of skilled workers to provide free reimbursement support services, including patient insurance benefit verification services, patient prior authorization services, and coverage appeals (collectively, "Support Services").

120. Lilly's drug reps and Covance field reps marketed the Support Services when detailing Lilly Covered Products to increase the likelihood that Prescribers would prescribe Lilly Covered Products. Put simply, in exchange for prescribing Lilly Covered Products, Lilly would assume the Prescribers' administrative responsibilities and costs associated with starting a patient on Lilly Covered Products. The more a Prescriber prescribed Lilly Covered Products as a percentage of its overall prescription volume, the greater the savings and profits to the practice, as time and money spent on Support Services for Lilly Covered Products would now be handled by Lilly. As detailed below, Lilly's Support Services were the "carrot" (remuneration) dangled to induce providers to prescribe Lilly Covered Products to their patients.

121. Support Services have a great value to Prescribers because they reduce, and in some instances eliminate, the administrative costs associated with prescribing drugs. These services also help increase profitability, particularly for office-based Prescribers, who derive most of their revenue from billing 15, 30, and 45-minute units of service provided to patients during office visits.

122. The technical term for an office visit is "evaluation and management services" or "E/M." In 2012, the most commonly billed Medicare physician service was the $70 "doctor office visit" for a 15-minute consultation, closely followed by the $100 "doctor office visit" for a 30-minute consultation. Medicare pays over $11 billion each year for E/M services alone. Medicaid and private insurers also pay billions each year.

123. When an office-based Prescriber receives payment for an E/M service, the payment is intended to compensate the Prescriber for medical care given *and* administrative tasks associated with that patient's care. These tasks include conducting the patient's prescription drug insurance benefit verification, determining if the drug is on the formulary lists and tiers, seeking a coverage determination, determining co-pays and deductibles, conducting telephone calls to patients, responding to patient complaints, returning messages and faxes, handling prescription refill requests, and, where necessary, obtaining "prior authorizations"[20] and managing the resulting paper trail.[21] Despite these enormous administrative costs and

[20] A study of 12 primary care practices published in the Journal of the American Board of Family Medicine put the mean annual projected cost per full-time equivalent physician for prior authorization activities between $2,161 and $3,430. The study's authors concluded that "preauthorization is a measurable burden on physician and staff time." *See* Christopher P. Morley, et al., *The Impact of Prior Authorization Requirements on Primary Care Physicians' Offices: Report of Two Parallel Network Studies*, 26 J. Am. Bd. Fam. Med. 93-95 (Jan.-Feb. 2013).

[21] In 2006, primary care providers spent a mean of 1.1 hours per week on authorizations, primary care nursing staffs spent 13.1 hours, and primary care clerical staff spent 5.6 hours, according to a 2009 study published in Health Affairs. The study estimated that the overall cost to the healthcare system of all practice interactions with health plans, including authorizations, was between $23 billion and $31 billion annually. *See* Lawrence P. Casalino, et. al., *What Does it Cost Physician Practices to Interact with Health Insurance Plans?*, 28 Health Affairs 533-543 (May 14, 2009), *available at* http://content.healthaffairs.org/content/28/4/w533.full.

expenses,[22] office-based Prescribers are not permitted, under federal or state regulations, to directly charge patients a fee for any of these services.[23] Instead, Prescribers get paid for these services indirectly, through the E/M unit charge.

124. Since a Prescriber's E/M reimbursement for each office visit is fixed per unit, Prescribers are continuously seeking ways to combat overhead costs and reduce expenses to earn more profit from each E/M unit billed.

125. One way to earn more profit is by reducing the administrative costs associated with prescribing drugs. If a Prescriber can reduce this cost, each E/M unit will be more profitable. These economics have a direct impact on a Prescriber's prescribing behavior. Prescribers are less likely to prescribe a drug that imposes an undue burden on support staff because doing so would mean a decrease in profitability resulting from the need to hire more staff or reduce the number of patients that can be seen in a day. Conversely, a Prescriber is much more likely to prescribe a drug if it can be prescribed with little or no administrative burden. Thus, the Prescriber's relative cost and burden in prescribing one company's drug when

[22] A 2011 study published in Health Affairs found that providers spend an annual average of nearly $83,000 of overhead staff time and costs associated with coverage plan issues. With approximately 835,000 physicians practicing in the nation, this translates to over $69 billion annually. *See* Dante Morra, et. al., *US Physician Practices Versus Canadian; Spending Nearly Four Times as Much Money Interacting with Payers,* 30 Health Affairs 1443-1450 (Aug. 3, 2011), *available at* http://content.healthaffairs.org/content/30/8/1443.full.pdf+html.

[23] For example, in Texas, "[p]roviders must certify that no charges beyond reimbursement paid under Texas Medicaid for covered services have been, or will be, billed to an eligible client." The Texas Medicaid Provider Procedures Manual makes clear to providers that "Federal regulations prohibit providers from charging clients a fee for completing or filing Medicaid claim forms" and notes that the "cost of claims filing is part of the usual and customary rate for doing business." Further, providers cannot charge "Texas Medicaid clients, their family, or the nursing facility for telephone calls, telephone consultations, or signing forms." Texas Medicaid Provider Procedures Manual § 1.6.9 (Dec. 2017), *available at* http://www.tmhp.com/Pages/Medicaid/Medicaid_Publications_Provider_manual.aspx (last accessed, Dec. 20, 2017).

compared to another company's drug can directly influence which drug a Prescriber will recommend to a patient.

126. These factors are not lost on pharmaceutical manufacturers like Lilly. Indeed, Lilly readily incurred the expense of providing Support Services knowing that these services would act as a powerful inducement to Prescribers to recommend the Lilly Covered Products over a competitor's products.

127. While pitching Prescribers, Lilly sales reps emphasized that, if the Prescribers prescribed Lilly Covered Products, Lilly would provide the services and resources of a full reimbursement support team to manage the administrative tasks associated with prescribing the drug. Lilly sales reps further emphasized that the cost and expenses normally associated with managing a patient's prescription would be shifted to Lilly, thereby increasing the Prescriber's bottom line.

128. This value proposition was a powerful tool in the hands of the Lilly drug representatives, and was used to induce Prescribers to recommend Lilly Covered Products.

129. Both CI-6, a Forteo drug rep, and CI-7, a Covance field reimbursement rep, confirmed that these Support Services were pitched to Prescribers and helped Lilly drive sales. In fact, CI-6 noted that offering reimbursement support services helped him promote Lilly Covered Products "[b]ecause [ ] it saves [Prescribers] time in getting [Lilly's] medication covered."

130. Because many drugs are expensive, most, if not all patients, cannot afford therapy unless it is covered by insurance. As a result, successfully starting patients on a drug therapy typically requires an initial determination to verify whether the patient has adequate prescription drug coverage. This process is called "benefit verification." For most Prescribers, the

verification of a patient is performed by staff and it is a time-consuming task. It can take multiple calls and over an hour just to determine the nature and extent of the patient's coverage. However, if the Prescriber recommends Lilly Covered Products, the verification task for the Lilly Covered Product is handled by Lilly-compensated specialists, rather than the Prescriber's staff.

131. Each day, Covance and UBC's offices receive requests from Prescribers to perform benefit verifications for patients. Each request is immediately forwarded to a verification specialist. The specialist verifies the source of the patient's primary and secondary insurance benefits (*i.e.*, private insurance, Medicare, TRICARE, and/or Medicaid), and contacts that insurer to verify the nature and extent of the patient's drug benefit coverage. In cases of Medicare and Medicaid, this is called a "coverage determination." For Medicare patients, coverage determinations tend to be particularly cumbersome and time consuming given the complexity of many Part D plans.[24]

132. In addition to verifications and coverage determinations, Lilly also provides prior authorization services. Many insurance carriers require a Prescriber to obtain a prior authorization before prescribing certain medications. Further, if a medication receives an authorization, that authorization may only be valid for a limited time, such as for one year or a month. After that, the Prescriber must start the prior authorization process over again. The most expensive Lilly Covered Products almost always require prior authorizations from a patient's

[24] These plans generally have four coverage phases: (1) the deductible phase, where patients pay 100% for drug costs until the deductible amount; (2) the initial coverage limit phase, where patients pay a percentage of the cost depending on the carrier and the drug's formulary position; (3) the coverage gap or "donut hole" phase, where in 2015 patients paid 45% of the cost for brand-name drugs and 65% of the cost for generic drugs; and (4) the catastrophic coverage phase, where in 2015 patients paid either 5% of the covered drug cost or $2.65 for generics and $6.60 for brand name drugs.

drug coverage plan, and, therefore, these services are particularly valuable to Prescribers. In fact, the cumbersome process often causes Prescribers to choose less expensive medications that do not require a prior authorization. Indeed, the Part D carriers use the prior authorization process as a means to contain costs associated with expensive drugs. Thus, if a Prescriber wants to recommend more expensive drugs, the Part D carriers require the Prescriber to go through the administrative process and make the case for prescribing the drug over a less expensive option. However, Lilly has relieved Prescribers of that burden in order to induce them to prescribe Lilly Covered Products over competing medications.

133. Lilly also provides a service to appeal authorization and coverage denials. If a patient's carrier denies coverage for Lilly Covered Products or denies the prior authorization request, Lilly takes steps to reverse the adverse determination.

134. The process of obtaining a prior authorization and/or appealing a denial requires direct input from the Prescriber regarding the patient's medical history, clinical and laboratory findings, and other information to establish the patient's medical necessity for a drug. The Prescriber and his or her staff must also develop specialized knowledge about each carrier's unique prior authorization and coverage criteria. Although these steps ordinarily require substantial time and expertise from the Prescriber and staff, Prescribers are not permitted to charge a fee separate from the E/M unit charge. Lilly arranged for personnel to handle prior authorizations and appeals, giving a clear advantage *and* tangible financial incentive to Prescribers who choose to prescribe Lilly Covered Products over competitors.

135. Support Services are widely used by physicians who prescribe the Lilly Covered Products. CI-6 estimates that 80% of Prescribers who prescribe Forteo utilize Support Services "because it's difficult to get some of these medications like Forteo and the growth hormones

covered." CI-6 also believes that Prescribers who receive Support Services from a pharmaceutical company are more likely to prescribe that company's drug over a competitor that does not provide such services.

136. The Support Services have real value to Prescribers. Without them, Prescribers would have to use their own staff and resources or outsource the Support Services to a private vendor. Lilly gives Prescribers a means to "outsource" this function without any direct or indirect cost to the Prescriber, but *only if* the Prescriber prescribes Lilly Covered Products.

DEFENDANTS' ILLEGAL CONDUCT GIVES RISE TO A DISTURBING CONFLICT OF INTEREST

137. Defendants' conduct creates a disturbing conflict of interest for the Prescribers and nurse educators involved therein. This conflict can harm patients and vastly increase pharmaceutical spending.

138. Medical professionals are expected to have no allegiance to or affiliation with any drug or drug company. Rather, medical professionals are duty-bound to make treatment decisions based solely upon the best interests of their patients. During recent years, scholars have raised concerns that increased promotional spending by pharmaceutical companies on nurses (mostly in the form of small gifts, dinners or drug samples) is creating a serious conflict, and have suggested that a ban or strong limitation on such conduct is needed to protect patients.[25]

139. The conflict created by Lilly's conduct, which extends far beyond simple gifts and drug samples, is significant. By using nurse educators to promote, and creating incentives for Prescribers to prescribe, the Lilly Covered Products, Lilly has created a conflict with the

[25] Nancy J. Crigger, Pharmaceutical Promotions and Conflict of Interest in Nurse Practitioner's Decision Making: The Undiscovered Country, 17 J. Am. Academy of Nurse Practitioners 207-12 (May 27, 2005).

Prescribers' duty of care to patients. The Prescribers and nurses may consciously or subconsciously recommend Lilly Covered Products despite cheaper alternatives or more effective treatments, to the detriment of a patient and the Government.[26]

140. The conflict of interest manifests in two related situations, continuity of care[27] and medication adherence. A Prescriber's decision to keep a patient on a certain drug or switch to a competing drug should be based on patient outcomes. Lilly's conduct, however, aligns the interest of the Prescribers and nurse educators with that of the drug company, to the detriment of the patients.

141. As CI-1 explained, "when you are going in you are being sent by Eli Lilly to conduct the program on Humalog products . . . . So you are not going to [go] in and talk about starting your patient first on Metformin when you are speaking for [Lilly] because [Metformin] is part of another drug."

142. Medication adherence benefits Lilly by increasing prescription refills. Yet, in the course of caring for patients, there may be times when a patient would have a better outcome by switching to a more effective drug or even a cheaper drug. Indeed, a Prescriber's decision to keep a patient on a certain drug or switch to a competing drug should be driven solely by patient outcomes. However, since the nurse educators and Prescribers' interests are aligned with Lilly's interest, their independence is compromised. Defendants' conduct thus not only violates the

[26] Judith A. Erlen, *Conflict of Interest – Nurses at Risk!*, 27 Orthopaedic Nursing 135-39 (Mar. – Apr. 2008). Erlen argues that a nurse simply accepting small gifts (such as notepads and promotional items) or listening to a marketing pitch is enough to cloud their judgment and create a conflict of interest. *Id.* at 137. This is a far cry from the situation highlighted here where the nurse *is indirectly employed* by the drug manufacturer.

[27] Continuity of care is concerned with quality of care over time. It is the process by which the patient and his/her physician-led care team are cooperatively involved in ongoing health care management toward the shared goal of high quality, cost-effective medical care.

AKS, but raises ethical and patient safety concerns for the nursing profession.

THE BREADTH OF LILLY'S KICKBACK SCHEME

143. The evidence uncovered during Relator's investigation reveals a kickback scheme of truly breathtaking proportions.

144. The scheme encompasses every Prescriber that, since at least 2007, received, directly or indirectly, "free nurse" services that were paid for by Lilly.

145. The scheme encompasses every Prescriber that, since 2007, received a visit from a nurse educator that purported to provide "education" on behalf of Lilly.

146. The scheme encompasses every Prescriber that, since at least 2008, received Support Services that were paid for by Lilly.

147. Lilly and its co-Defendants profited from the illegal schemes described in this Complaint, and Medicare, Medicaid, TRICARE, and Veteran Administration Healthcare were made to bear the costs.

148. Since at least 2007, Defendants' actions knowingly have caused pharmacies, PBMs, Part D sponsors, fiscal intermediaries and others to submit millions of dollars in claims to Government programs for Lilly Covered Products provided to beneficiaries as a result of Defendants' illegal marketing and quid pro quo arrangements. Those false claims have caused the Government to disburse billions of dollars in reimbursements that were tainted by kickbacks and should not have been paid.

149. The following are just some examples of Prescribers who received the free nurse education services or Support Services offered by Defendants in part to induce a recommendation of the Lilly Covered Products:

- Prescriber 1, a doctor located in Hammonton, New Jersey. Prescriber 1

was among the 1,000 highest prescribers of Humalog to Medicare patients in 2012 and 2013. CI-1 provided nurse education services to Prescriber 1's Humalog patients. CI-1 typically educated approximately 10-12 of Prescriber 1's patients per month.

- Prescriber 2, a doctor located in Tampa, Florida. Prescriber 2 was among the 1,000 highest prescribers of Humalog to Medicare patients in 2014. CI-2, a nurse educator, called upon Prescriber 2 from 2005 to 2015 in a sales capacity and to train Prescriber 2's staff.

- Prescriber 3, a doctor located in Tampa, Florida. CI-2 provided nurse education services to Humalog patients, including patients of Prescriber 3 from 2008 to 2015.

- Prescriber 4, a doctor located in Tampa Florida. CI-2 provided nurse education services to Humalog and Humulin patients, including patients of Prescriber 4 from 2011 or 2012 until 2015.

- Prescriber 5, a doctor located in McKenzie, Tennessee. Prescriber 5 was among the 1,000 highest prescribers of Forteo to Medicare patients in 2014 and 2015. CI-5 provided nurse education services to Forteo patients, including patients of Prescriber 5 from approximately 2005 to 2015.

- Prescriber 6, a doctor located in Jackson, Tennessee. Prescriber 6 was among the 1,000 highest prescribers of Forteo to Medicare patients in 2014 and 2015. CI-5 provided nurse education services to Forteo patients, including patients of Prescriber 6 from approximately 2004 or 2005 to 2015.

- Prescriber 7, a doctor located in Martinsburg, West Virginia. Prescriber 7 was among the 1,000 highest prescribers of Forteo to Medicare patients in 2014 and 2015. CI-7 provided Support Services to Forteo patients, including patients of Prescriber 7 in 2015.

- Prescriber 8, a doctor located in Morgantown, West Virginia. Prescriber 8 was among the 1,000 highest prescribers of Forteo to Medicare patients in 2014 and 2015. CI-7 provided Support Services to Forteo patients, including patients of Prescriber 8 in 2015.

150. Defendants employed the three schemes detailed above across the nation, and the Lilly Covered Products were marketed, prescribed, and sold nationwide. Claims were submitted to federal and state healthcare programs, including Medicare and Medicaid, in most, if not all, states for each of the Lilly Covered Products. By way of some examples, approximate Medicare

claim data concerning the Lilly Covered Products for certain years is summarized in the paragraphs below.

151. **Humalog.**[28] Approximately 189,000 Medicare Part D Claims for Humalog were submitted nationwide in 2015. The total Part D spending for this drug in 2015 was approximately $114 million. Over $1 million was spent in each of 28 states. The top 5 states in terms of spending were Florida ($10.7 million), Texas ($9.78 million), California ($8.2 million), Pennsylvania ($6.54 million), and Georgia ($5.19 million). A further breakdown of each state's 2015 Medicare claim data for Humalog is summarized in the table below.

2015 Humalog Medicare Claim Data
(approximate values)

State	Patients	Claims	Cost (in millions)
Alabama	1,126	5,651	$3.4
Alaska	18	61	$0.0388
Arizona	628	2,634	$1.71
Arkansas	409	2,212	$1.32
California	2,887	14,586	$8.2
Colorado	187	845	$0.571
Connecticut	341	1,691	$1.2
Delaware	82	377	$0.276
District of Columbia	72	270	$0.129
Florida	3,828	18,342	$10.7
Georgia	1,768	9,040	$5.19
Hawaii	68	285	$0.177
Idaho	60	393	$0.21
Illinois	1,671	8,536	$4.93
Indiana	879	4,415	$2.86
Iowa	165	896	$0.459
Kansas	128	693	$0.381

[28] *Prescriber Checkup: Humalog*, ProPublica, *available at* https://projects.propublica.org/checkup/drugs/130 (last accessed Dec. 19, 2017).

2015 Humalog Medicare Claim Data (approximate values)			
State	**Patients**	**Claims**	**Cost (in millions)**
Kentucky	987	5,267	$3.59
Louisiana	672	3,288	$1.87
Maine	127	729	$0.423
Maryland	438	2,008	$1.16
Massachusetts	1,017	5,834	$3.45
Michigan	1,290	5,956	$4.36
Minnesota	266	1,455	$0.723
Mississippi	1,006	5,004	$3.1
Missouri	543	2,761	$1.73
Montana	50	285	$0.19
Nebraska	122	789	$0.393
Nevada	165	672	$0.453
New Hampshire	121	624	$0.373
New Jersey	1,067	5,065	$2.95
New Mexico	152	658	$0.359
New York	1,616	9,062	$4.87
North Carolina	1,425	7,632	$4.35
North Dakota	37	228	$0.0979
Ohio	1,211	5,711	$3.81
Oklahoma	286	1,342	$0.815
Oregon	255	1,342	$0.828
Pennsylvania	1,972	11,476	$6.54
Rhode Island	217	1,185	$0.675
South Carolina	997	5,035	$3.02
South Dakota	42	321	$0.163
Tennessee	1,546	7,344	$4.81
Texas	3,223	14,578	$9.78
Utah	127	597	$0.444
Vermont	38	231	$0.19
Virginia	1,105	5,610	$3.28
Washington	336	1,675	$1.04
West Virginia	314	1,720	$1.18
Wisconsin	384	2,146	$1.32
Wyoming	23	94	$0.0531

2015 Humalog Medicare Claim Data (approximate values)			
State	**Patients**	**Claims**	**Cost (in millions)**
Total	37,494	188,651	$114.14

152. **Humulin.**[29] In 2011, approximately 503,000 Medicare Part D Claims were submitted, resulting in approximately $40.7 million in nationwide spending for Humulin. Approximately 435,000 Medicare Part D Claims were submitted in 2012, resulting in approximately $41.7 million in nationwide spending for Humulin. In 2013, approximately 438,000 Medicare Part D Claims were submitted, resulting in approximately $50.2 million in nationwide spending for Humulin. Approximately 425,000 Medicare Part D Claims were submitted in 2014, resulting in approximately $58.1 million in nationwide spending for Humulin.

153. In 2015, approximately 404,000 Medicare Part D Claims for Humulin were submitted, resulting in approximately $64 million in nationwide spending. Over $1 million was spent in each of 22 states. The top 3 states in terms of spending were California ($12.2 million), Texas ($6.2 million), and Florida ($4.78 million). A further breakdown of each state's 2015 Medicare claim data for Humulin is summarized in the table below.

2015 Humulin Medicare Claim Data (approximate values)			
State	**Patients**	**Claims**	**Cost (in millions)**
Alabama	2,629	10,139	$1.66
Alaska	40	131	$0.0284
Arizona	1,354	4,284	$0.772
Arkansas	1,663	6,178	$1.04
California	32,755	102,702	$12.2
Colorado	2,340	7,809	$0.843

[29] *Prescriber Checkup: Humulin*, ProPublica, *available at* https://projects.propublica.org/checkup/drugs/5410 (last accessed Dec. 19, 2017).

2015 Humulin Medicare Claim Data (approximate values)			
State	**Patients**	**Claims**	**Cost (in millions)**
Connecticut	536	1,780	$0.313
Delaware	114	419	$0.0882
District of Columbia	158	450	$0.0553
Florida	7,704	26,275	$4.78
Georgia	3,785	14,127	$2.06
Hawaii	559	1,706	$0.189
Idaho	265	878	$0.203
Illinois	3,675	14,373	$2.5
Indiana	1,581	5,844	$1.28
Iowa	451	1,630	$0.291
Kansas	417	1,775	$0.368
Kentucky	1,921	7,270	$1.34
Louisiana	2,094	8,143	$1.15
Maine	388	1,634	$0.318
Maryland	1,019	3,129	$0.426
Massachusetts	1,292	4,559	$0.861
Michigan	2,146	6,795	$1.46
Minnesota	619	2,190	$0.414
Mississippi	1,795	7,053	$1.06
Missouri	1,292	4,950	$1.09
Montana	130	448	$0.0855
Nebraska	279	1,139	$0.213
Nevada	688	2,184	$0.435
New Hampshire	217	960	$0.183
New Jersey	1,747	6,704	$1.14
New Mexico	367	1,069	$0.206
New York	5,124	19,510	$2.67
North Carolina	2,614	9,988	$1.82
North Dakota	100	289	$0.0587
Ohio	3,753	12,646	$2.64
Oklahoma	1,278	5,270	$0.964
Oregon	2,332	8,813	$1.32
Pennsylvania	3,167	13,231	$2.18
Rhode Island	225	829	$0.15

2015 Humulin Medicare Claim Data (approximate values)			
State	**Patients**	**Claims**	**Cost (in millions)**
South Carolina	633	2,105	$0.42
South Dakota	220	837	$0.179
Tennessee	3,426	12,985	$2.2
Texas	9,839	36,107	$6.21
Utah	398	1,526	$0.264
Vermont	54	182	$0.0396
Virginia	1,792	6,731	$1.15
Washington	2,026	6,998	$1.19
West Virginia	718	2,757	$0.461
Wisconsin	1,069	4,112	$0.961
Wyoming	97	360	$0.0734
Total	114,885	404,003	$64

154. **Forteo.**[30] In 2011, approximately 186,000 Medicare Part D Claims were submitted, resulting in approximately $215 million in nationwide spending for Forteo. Approximately 188,000 Medicare Part D Claims were submitted in 2012, resulting in approximately $245 million in nationwide spending for Forteo. In 2013, approximately 207,000 Medicare Part D Claims were submitted, resulting in approximately $307 million in nationwide spending for Forteo. Approximately 208,000 Medicare Part D Claims were submitted in 2014, resulting in approximately $358 million in nationwide spending for Forteo.

155. In 2015, approximately 192,000 Medicare Part D Claims for Forteo were submitted, resulting in approximately $424 million in nationwide spending. Over $10 million was spent in each of 12 states. The top 5 states in terms of spending were California ($54.1 million), Texas ($44.5 million), Florida ($32.9 million), New York ($29.9 million), and

[30] *Prescriber Checkup: Forteo*, ProPublica, *available at* https://projects.propublica.org/checkup/drugs/6464 (last accessed Dec. 19, 2017).

Pennsylvania ($19.3 million). A further breakdown of each state's 2015 Medicare claim data for Forteo is summarized in the table below.

2015 Forteo Medicare Claim Data
(approximate values)

State	Patients	Claims	Cost (in millions)
Alabama	631	3,419	$7.25
Alaska	65	287	$0.727
Arizona	796	4,113	$9.23
Arkansas	402	2,341	$4.85
California	4,654	25,973	$54.1
Colorado	848	4,756	$10.6
Connecticut	397	2,084	$5.24
Delaware	87	404	$0.94
District of Columbia	35	124	$0.307
Florida	2,925	14,974	$32.9
Georgia	872	4,294	$9.83
Hawaii	403	2,426	$5.14
Idaho	168	866	$1.83
Illinois	976	5,342	$11.8
Indiana	833	4,407	$9.93
Iowa	236	1,330	$2.84
Kansas	244	1,465	$3.13
Kentucky	711	3,865	$8.49
Louisiana	314	1,669	$3.56
Maine	127	717	$1.64
Maryland	372	1,820	$4.45
Massachusetts	440	2,191	$5.15
Michigan	1,349	7,543	$16.9
Minnesota	535	2,915	$6.54
Mississippi	257	1,364	$2.98
Missouri	677	3,692	$8.02
Montana	84	408	$0.87
Nebraska	117	709	$1.46
Nevada	147	678	$1.51
New Hampshire	124	644	$1.46
New Jersey	1,015	5,169	$12.7

2015 Forteo Medicare Claim Data (approximate values)			
State	**Patients**	**Claims**	**Cost (in millions)**
New Mexico	157	903	$1.98
New York	2,488	13,067	$29.9
North Carolina	1,047	5,047	$11.8
North Dakota	146	895	$1.93
Ohio	1,263	7,387	$16.6
Oklahoma	587	3,100	$6.62
Oregon	269	1,507	$3.18
Pennsylvania	1,499	8,680	$19.3
Rhode Island	46	279	$0.583
South Carolina	624	3,014	$7.07
South Dakota	81	528	$1.11
Tennessee	1,142	5,967	$13.1
Texas	3,898	20,651	$44.5
Utah	199	994	$2.19
Vermont	31	172	$0.417
Virginia	488	2,354	$5.77
Washington	435	2,350	$5.05
West Virginia	112	518	$1.25
Wisconsin	411	2,362	$5.09
Wyoming	30	133	$0.341
Total	35,794	191,897	$424.16

156. By way of some examples, approximate Medicaid claim data concerning the Lilly Covered Products for certain states for certain years is summarized in the paragraphs below.

157. **Connecticut.** In the designated years, Medicaid paid at least the following approximate amounts for prescriptions of the Lilly Covered Products filled in Connecticut:

Connecticut Medicaid Claim Data (approximate values based on available data)						
Drug	**Forteo**		**Humalog**		**Humulin**	
	Claims	**Payments**	**Claims**	**Payments**	**Claims**	**Payments**
2012	83	$67,000	20692	$5,624,000	7891	$1,292,000
2013	88	$121,000	21611	$6,957,000	6914	$1,484,000

Connecticut Medicaid Claim Data (approximate values based on available data)						
Drug	**Forteo**		**Humalog**		**Humulin**	
	Claims	**Payments**	**Claims**	**Payments**	**Claims**	**Payments**
2014	73	$134,000	18998	$7,913,000	4913	$1,384,000
2015	136	$325,000	27718	$13,973,000	5828	$2,188,000
2016	204	$628,000	29666	$17,787,000	5455	$2,687,000

158. **Florida.** In the designated years, Medicaid paid at least the following approximate amounts for prescriptions of the Lilly Covered Products filled in Florida:

Florida Medicaid Claim Data (approximate values based on available data)						
Drug	**Forteo**		**Humalog**		**Humulin**	
	Claims	**Payments**	**Claims**	**Payments**	**Claims**	**Payments**
2012	473	$551,000	75826	$18,261,000	927	$597,000
2013	698	$952,000	74019	$21,274,000	1180	$1,134,000
2014	508	$829,000	73377	$26,083,000	1353	$1,511,000
2015	454	$961,000	78652	$32,930,000	1408	$1,853,000
2016	637	$1,653,000	81219	$37,814,000	1141	$1,627,000

159. **Illinois**. Medicaid paid at least the following approximate amounts for prescriptions of the Lilly Covered Products filled in Illinois in the designated years:

Illinois Medicaid Claim Data (approximate values based on available data)						
Drug	**Forteo**		**Humalog**		**Humulin**	
	Claims	**Payments**	**Claims**	**Payments**	**Claims**	**Payments**
2012	43	$168,000	44826	$25,829,000	20850	$6,793,000
2013	40	$165,000	43099	$28,685,000	16930	$6,863,000
2014	61	$291,000	53454	$42,395,000	19306	$8,864,000
2015	69	$505,000	57623	$56,748,000	18616	$11,464,000
2016	62	$510,000	55408	$65,396,000	16107	$12,532,000

160. **Iowa.** Medicaid paid at least the following approximate amounts for prescriptions of the Lilly Covered Products filled in Iowa in the designated years:

Iowa Medicaid Claim Data (approximate values based on available data)						
Drug	**Forteo**		**Humalog**		**Humulin**	
	Claims	**Payments**	**Claims**	**Payments**	**Claims**	**Payments**
2012	73	$80,000	7867	$1,416,000	1820	$286,000
2013	26	$32,000	8121	$1,447,000	1468	$363,000
2014	59	$69,000	11878	$3,126,000	2033	$615,000
2015	113	$208,000	22752	$7,871,000	3722	$1,310,000

161. **New Jersey**. Medicaid paid at least the following approximate amounts for prescriptions of the Lilly Covered Products filled in New Jersey in the designated years:

New Jersey Medicaid Claim Data (approximate values based on available data)						
Drug	**Forteo**		**Humalog**		**Humulin**	
	Claims	**Payments**	**Claims**	**Payments**	**Claims**	**Payments**
2013	305	$294,000	31389	$8,291,000	11136	$1,831,000
2014	353	$426,000	59302	$19,565,000	20459	$3,940,000
2015	352	$675,000	61580	$24,855,000	18925	$4,698,000
2016	336	$825,000	61459	$24,100,000	16366	$3,956,000

162. **North Carolina.** In the designated years, Medicaid paid at least the following approximate amounts for prescriptions of the Lilly Covered Products filled in North Carolina:

North Carolina Medicaid Claim Data (approximate values based on available data)						
Drug	**Forteo**		**Humalog**		**Humulin**	
	Claims	**Payments**	**Claims**	**Payments**	**Claims**	**Payments**
2012	278	$295,000	18853	$4,631,000	14983	$2,509,000
2013	245	$273,000	19963	$5,156,000	13946	$3,290,000
2014	294	$339,000	20446	$5,499,000	15104	$3,919,000
2015	276	$425,000	19300	$5,981,000	14777	$4,584,000
2016	338	$655,000	19409	$6,604,000	13571	$4,524,000

163. **Texas.** Medicaid paid at least the following approximate amounts for claims submitted in the designated years for prescriptions of the Lilly Covered Products filled in Texas:

Texas Medicaid Claim Data (approximate values based on available data)						
Drug	**Forteo**		**Humalog**		**Humulin**	
	Claims	**Payments**	**Claims**	**Payments**	**Claims**	**Payments**
2012	1060	$1,267,000	31358	$9,328,000	17634	$3,087,000
2013	1113	$1,433,000	39275	$10,214,000	13571	$2,942,000
2014	1017	$1,527,000	35554	$13,134,000	35228	$6,859,000
2015	1043	$1,998,000	39002	$17,109,000	37972	$9,272,000
2016	1032	$2,554,000	39157	$19,088,000	34903	$9,929,000

COUNT 1 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE FALSE CLAIMS ACT:
PRESENTING FALSE CLAIMS FOR PAYMENT (31 U.S.C. § 3729(a)(1)(A))

164. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

165. Relator seeks relief against Defendants under Section 3729(a)(1)(A) of the FCA, 31 U.S.C. § 3729(a)(1)(A).

166. As a result of Lilly offering or paying, and Lilly's co-Defendants, physicians, and other health care professionals soliciting or receiving, kickbacks to purchase, order, or recommend the purchasing or ordering of Lilly Covered Products in violation of the federal AKS, 42 U.S.C. § 1320a-7b(b)(1) and (b)(2), Defendants caused false and fraudulent claims for payment to be presented to federal health care programs.

167. Accordingly, Defendants knowingly caused to be presented false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1)(A).

168. By reason of the false or fraudulent claims that Defendants knowingly caused to be presented to federal health care programs, the United States has been damaged in a substantial amount to be determined at trial, and is entitled to recover treble damages plus a civil monetary penalty for each false claim.

**COUNT 2 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE FALSE CLAIMS ACT:
USE OF FALSE STATEMENTS (31 U.S.C. § 3729(a)(1)(B))**

169. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

170. Relator seeks relief against Defendants under Section 3729(a)(1)(B) of the FCA, 31 U.S.C. § 3729(a)(1)(B).

171. As a result of Lilly offering or paying, and Lilly's co-Defendants, physicians, and other health care professionals soliciting or receiving, kickbacks to purchase, order, or recommend purchasing or ordering Lilly Covered Products in violation of the federal AKS, 42 U.S.C. § 1320a-7b(b)(1) and (b)(2), Defendants knowingly caused pharmacies, PBMs, Part D sponsors, fiscal intermediaries, and others to make false records or statements that were material to getting false or fraudulent claims paid by federal health care programs.

172. More specifically, the pharmacies, PBMs, Part D sponsors, fiscal intermediaries, and others, falsely certified, and/or represented that the reimbursements they sought for Lilly Covered Products were in full compliance with applicable federal and state laws prohibiting fraudulent and false reporting, including but not limited to the AKS. Those false certifications, statements, or representations caused federal health care programs to pay out sums that would not have been paid if those programs had been made aware of the falsity of the certifications, statements, or representations.

173. Accordingly, Defendants caused the use of false records or statements material to false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1)(B).

174. By reason of these false records or statements, the United States has been damaged in a substantial amount to be determined at trial, and is entitled to treble damages plus a

monetary civil penalty for each false record or statement.

**COUNT 3 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE FALSE CLAIMS ACT:
CONSPIRING TO VIOLATE THE FALSE CLAIMS ACT (31 U.S.C. § 3729(a)(1)(C))**

175. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

176. Relator seeks relief against Defendants under Section 3729(a)(1)(C) of the FCA, 31 U.S.C. § 3729(a)(1)(C).

177. As set forth above, Lilly conspired with Lilly's co-Defendants, physicians, and other health care professionals to offer or pay kickbacks in exchange for, or to induce them to purchase, order, or recommend the purchasing or ordering of Lilly Covered Products in violation of the federal AKS, 42 U.S.C. § 1320a-7b(b)(1) and (b)(2), thereby causing false and fraudulent claims to be presented to federal health care programs seeking reimbursement for Lilly Covered Products dispensed in connection with the kickback scheme.

178. Accordingly, Defendants conspired to commit violations of 31 U.S.C. §§ 3729(a)(1)(A) and 3729(a)(1)(B), in violation of 31 U.S.C. § 3729(a)(1)(C).

179. By reason of the Defendants conspiracy to violate 31 U.S.C. §§ 3729(a)(1)(A) and 3729(a)(1)(B), the United States has been damaged in a substantial amount to be determined at trial, and is entitled to recover treble damages plus a civil monetary penalty for each false claim.

**COUNT 4 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE ARKANSAS MEDICAID FRAUD FALSE CLAIMS ACT,
ARK. CODE ANN. §§ 20-77-901 – 20-77-911**

180. This is a claim for treble damages and civil penalties under the Arkansas Medicaid Fraud False Claims Act, Ark. Code Ann. §§ 20-77-901 – 20-77-911. Relator realleges

and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

181. Defendants violated the Arkansas Medicaid Fraud False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Arkansas as described herein.

182. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Arkansas.

183. The State of Arkansas, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Arkansas would not otherwise have paid.

184. By reason of these payments, the State of Arkansas has been damaged, and continues to be damaged, in a substantial amount.

COUNT 5 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE CALIFORNIA FALSE CLAIMS ACT,
CAL. GOV'T CODE §§ 12650 – 12656

185. This is a claim for treble damages and civil penalties under the California False Claims Act, Cal. Gov't Code §§ 12650 – 12656. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

186. Defendants violated the California False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of California as described herein.

187. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of California.

188. The State of California, unaware of the false or fraudulent nature of these claims,

paid such claims which the State of California would not otherwise have paid.

189. By reason of these payments, the State of California has been damaged, and continues to be damaged, in a substantial amount.

**COUNT 6 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE COLORADO MEDICAID FALSE CLAIMS ACT,
COL. REV. STAT. ANN. §§ 25.5-4-303.5 – 25.5-4-310**

190. This is a claim for treble damages and civil penalties under the Colorado Medicaid False Claims Act, Colo. Rev. Stat. §§ 25.5-4-303.5 – 25.5-4-310. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

191. Defendants violated the Colorado Medicaid False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Colorado, as described herein.

192. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Colorado.

193. The State of Colorado, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Colorado would not otherwise have paid.

194. By reason of these payments, the State of Colorado has been damaged, and continues to be damaged, in a substantial amount.

**COUNT 7 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE CONNECTICUT FALSE CLAIMS AND OTHER PROHIBITED ACTS UNDER STATE-ADMINISTERED HEALTH OR HUMAN SERVICES ACT ("CONNECTICUT FALSE CLAIMS ACT"),
CONN. GEN. STAT. ANN. §§ 4-274 – 4-289**

195. This is a claim for treble damages and civil penalties under the Connecticut False Claims Act, Conn. Gen. Stat. Ann. §§ 4-274 – 4-289. Relator realleges and incorporates the

allegations in the preceding paragraphs as if set forth fully herein.

196. Defendants violated the Connecticut False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Connecticut, as described herein.

197. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Connecticut.

198. The State of Connecticut, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Connecticut would not otherwise have paid.

199. By reason of these payments, the State of Connecticut has been damaged, and continues to be damaged, in a substantial amount.

COUNT 8 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE DELAWARE FALSE CLAIMS AND REPORTING ACT,
DEL. C. ANN. TIT. 6, §§ 1201 – 1211

200. This is a claim for treble damages and civil penalties under the Delaware False Claims and Reporting Act, Del. C. Ann. tit. 6, §§ 1201 – 1211. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

201. Defendants violated the Delaware False Claims and Reporting Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Delaware, as described herein.

202. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Delaware.

203. The State of Delaware, unaware of the false or fraudulent nature of these claims,

paid such claims which the State of Delaware would not otherwise have paid.

204. By reason of these payments, the State of Delaware has been damaged, and continues to be damaged, in a substantial amount.

COUNT 9 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE DISTRICT OF COLUMBIA
MEDICAID FRAUD ENFORCEMENT
AND RECOVERY AMENDMENT ACT OF 2012,
D.C. CODE ANN. §§ 2-381.01 – 2-381.10

205. This is a claim for treble damages and civil penalties under District of Columbia Medicaid Fraud Enforcement and Recovery Amendment Act of 2012, D.C. Code Ann. §§ 2-381.01 – 2-381.10. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

206. Defendants violated the District of Columbia Medicaid Fraud Enforcement and Recovery Amendment Act of 2012 by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the District of Columbia, as described herein.

207. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the District of Columbia.

208. The District of Columbia, unaware of the false or fraudulent nature of these claims, paid such claims which the District of Columbia would not otherwise have paid.

209. By reason of these payments, the District of Columbia has been damaged, and continues to be damaged, in a substantial amount.

**COUNT 10 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE FLORIDA FALSE CLAIMS ACT,
FLA. STAT. ANN. §§ 68.081 – 68.092**

210. This is a claim for treble damages and civil penalties under the Florida False Claims Act, Fla. Stat. Ann. §§ 68.081 – 68.092. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

211. Defendants violated the Florida False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Florida as described herein.

212. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Florida.

213. The State of Florida, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Florida would not otherwise have paid.

214. By reason of these payments, the State of Florida has been damaged, and continues to be damaged, in a substantial amount.

**COUNT 11 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE GEORGIA FALSE MEDICAID CLAIMS ACT,
GA. CODE ANN. §§ 49-4-168 – 49-4-168.6**

215. This is a claim for treble damages and civil penalties under Georgia False Medicaid Claims Act, Ga. Code Ann. §§ 49-4-168 – 49-4-168.6. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

216. Defendant violated the Georgia False Medicaid Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Georgia, as described herein.

217. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Georgia.

218. The State of Georgia, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Georgia would not otherwise have paid.

219. By reason of these payments, the State of Georgia has been damaged, and continues to be damaged, in a substantial amount.

COUNT 12 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE HAWAII FALSE CLAIMS TO THE STATE ACT,
HAW. REV. STAT. §§ 661-21 – 661-31

220. This is a claim for treble damages and civil penalties under the Hawaii False Claims to the State Act, Haw. Rev. Stat. §§ 661-21 – 661-31. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

221. Defendants violated the Hawaii False Claims to the State Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Hawaii, as described herein.

222. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Hawaii.

223. The State of Hawaii, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Hawaii would not otherwise have paid.

224. By reason of these payments, the State of Hawaii has been damaged, and continues to be damaged, in a substantial amount.

**COUNT 13 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE ILLINOIS FALSE CLAIMS ACT,
740 ILL. COMP. STAT. ANN. §§ 175/1 – 175/8**

225. This is a claim for treble damages and civil penalties under the Illinois False Claims Act, 740 Ill. Comp. Stat. Ann. §§ 175/1 – 175/8. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

226. Defendants violated the Illinois False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Illinois, as described herein.

227. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Illinois.

228. The State of Illinois, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Illinois would not otherwise have paid.

229. By reason of these payments, the State of Illinois has been damaged, and continues to be damaged, in a substantial amount.

**COUNT 14 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE INDIANA FALSE CLAIMS
AND WHISTLEBLOWER PROTECTION ACT,
IND. CODE ANN. §§ 5-11-5.5-1 – 5-11-5.5-18**

230. This is a claim for treble damages and civil penalties under the Indiana False Claims and Whistleblowers Protection Act, Ind. Code Ann. §§ 5-11-5.5-1 – 5-11-5.5-18. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

231. Defendants violated the Indiana False Claims and Whistleblowers Protection Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Indiana, as described herein.

232. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Indiana.

233. The State of Indiana, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Indiana would not otherwise have paid.

234. By reason of these payments, the State of Indiana has been damaged, and continues to be damaged, in a substantial amount.

COUNT 15 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE IOWA FALSE CLAIMS ACT,
IOWA CODE ANN. §§ 685.1 – 685.7

235. This is a claim for treble damages and civil penalties under the Iowa False Claims Act, Iowa Code Ann. §§ 685.1 – 685.7. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

236. Defendants violated the Iowa False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Iowa, as described herein.

237. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Iowa.

238. The State of Iowa, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Iowa would not otherwise have paid.

239. By reason of these payments, the State of Iowa has been damaged, and continues to be damaged, in a substantial amount.

**COUNT 16 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE LOUISIANA
MEDICAL ASSISTANCEPROGRAMS INTEGRITY LAW,
LA. STAT. ANN. §§ 437.1 – 440.16**

240. This is a claim for treble damages and civil penalties under the Louisiana Medical Assistance Programs Integrity Law, La. Stat. Ann. §§ 437.1 – 440.16. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

241. Defendants violated the Louisiana Medical Assistance Programs Integrity Law by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Louisiana, as described herein.

242. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Louisiana.

243. The State of Louisiana, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Louisiana would not otherwise have paid.

244. By reason of these payments, the State of Louisiana has been damaged, and continues to be damaged, in a substantial amount.

**COUNT 17 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE MARYLAND FALSE HEALTH CLAIMS ACT,
MD. CODE ANN., HEALTH-GEN. §§ 8-101 – 8-111**

245. This is a claim for treble damages and civil penalties under the Maryland False Health Claims Act, Md. Code Ann., Health-General §§ 8-101 – 8-111. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

246. Defendants violated the Maryland False Health Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Maryland, as described herein.

247. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Maryland.

248. The State of Maryland, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Maryland would not otherwise have paid.

249. By reason of these payments, the State of Maryland has been damaged, and continues to be damaged, in a substantial amount.

COUNT 18 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE MASSACHUSETTS FALSE CLAIMS LAW,
MASS. GEN. LAWS ANN. CH. 12, §§ 5A – 5O

250. This is a claim for treble damages and civil penalties under the Massachusetts False Claims Law, Mass. Gen. Laws Ann. ch. 12, §§ 5A – 5O. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

251. Defendants violated the Massachusetts False Claims Law by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the Commonwealth of Massachusetts, as described herein.

252. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Commonwealth of Massachusetts.

253. The Commonwealth of Massachusetts, unaware of the false or fraudulent nature of these claims, paid such claims which the Commonwealth of Massachusetts would not otherwise have paid.

254. By reason of these payments, the Commonwealth of Massachusetts has been damaged, and continues to be damaged, in a substantial amount.

**COUNT 19 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE MICHIGAN MEDICAID FALSE CLAIM ACT,
MICH. COMP. LAWS ANN. §§ 400.601 – 400.615**

255. This is a claim for treble damages and civil penalties under the Michigan Medicaid False Claim Act, Mich. Comp. Laws Ann. §§ 400.601 – 400.615. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

256. Defendants violated the Michigan Medicaid False Claim Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Michigan, as described herein.

257. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Michigan.

258. The State of Michigan, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Michigan would not otherwise have paid.

259. By reason of these payments, the State of Michigan has been damaged, and continues to be damaged, in a substantial amount.

**COUNT 20 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE MINNESOTA FALSE CLAIMS ACT,
MINN. STAT. ANN. §§ 15C.01 – 15C.16**

260. This is a claim for treble damages and civil penalties under the Minnesota False Claims Act, Minn. Stat. Ann. §§ 15C.01 – 15C.16. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

261. Defendants violated the Minnesota False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Minnesota, as described herein.

262. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Minnesota.

263. The State of Minnesota, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Minnesota would not otherwise have paid.

264. By reason of these payments, the State of Minnesota has been damaged, and continues to be damaged, in a substantial amount.

COUNT 21 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE MONTANA FALSE CLAIMS ACT,
MONT. CODE ANN. §§ 17-8-401 – 17-8-416

265. This is a claim for treble damages and civil penalties under Montana False Claims Act, Mont. Code Ann. §§ 17-8-401 – 17-8-416. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

266. Defendants violated the Montana False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Montana, as described herein.

267. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Montana.

268. The State of Montana, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Montana would not otherwise have paid.

269. By reason of these payments, the State of Montana has been damaged, and continues to be damaged, in a substantial amount.

COUNT 22 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE NEVADA SUBMISSION OF FALSE CLAIMS TO STATE OR LOCAL GOVERNMENT ACT, NEV. REV. STAT. ANN. §§ 357.010 – 357.250

270. This is a claim for treble damages and civil penalties under the Nevada Submission of False Claims to State or Local Government Act, Nev. Rev. Stat. Ann. §§ 357.010 – 357.250. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

271. Defendants violated the Nevada Submission of False Claims to State or Local Government Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Nevada, as described herein.

272. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Nevada.

273. The State of Nevada, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Nevada would not otherwise have paid.

274. By reason of these payments, the State of Nevada has been damaged, and continues to be damaged, in a substantial amount.

COUNT 23 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE NEW HAMPSHIRE MEDICAID FRAUD AND FALSE CLAIMS LAW, N.H. REV. STAT. ANN. §§ 167:61-B – 167:61-E

275. This is a claim for treble damages and civil penalties under the New Hampshire Medicaid Fraud and False Claims Law, N.H. Rev. Stat. Ann. §§ 167:61-b – 167:61-e. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

276. Defendants violated the New Hampshire Medicaid Fraud and False Claims Law

by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of New Hampshire, as described herein.

277. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of New Hampshire.

278. The State of New Hampshire, unaware of the false or fraudulent nature of these claims, paid such claims which the State of New Hampshire would not otherwise have paid.

279. By reason of these payments, the State of New Hampshire has been damaged, and continues to be damaged, in a substantial amount.

COUNT 24 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE NEW JERSEY FALSE CLAIMS ACT,
N.J. STAT. ANN. §§ 2A:32C-1 – 2A:32C-18

280. This is a claim for treble damages and civil penalties under the New Jersey False Claims Act, N.J. Stat. Ann. §§ 2A:32C-1 – 2A:32C-18. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

281. Defendants violated the New Jersey False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of New Jersey, as described herein.

282. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of New Jersey.

283. The State of New Jersey, unaware of the false or fraudulent nature of these claims, paid such claims which the State of New Jersey would not otherwise have paid.

284. By reason of these payments, the State of New Jersey has been damaged, and

continues to be damaged, in a substantial amount.

**COUNT 25 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE NEW MEXICO FRAUD AGAINST TAXPAYERS ACT,
N.M. STAT. ANN. §§ 44-9-1 – 44-9-14,
AND THE NEW MEXICO MEDICAID FALSE CLAIMS ACT,
N.M. STAT. ANN. §§ 27-14-1 – 27-14-15**

285. This is a claim for treble damages and civil penalties under the New Mexico Fraud Against Taxpayers Act, N.M. Stat. Ann. §§ 44-9-1 – 44-9-14, and the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. §§ 27-14-1 – 27-14-15. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

286. Defendants violated the New Mexico Fraud Against Taxpayers Act and the New Mexico Medicaid False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of New Mexico, as described herein.

287. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of New Mexico.

288. The State of New Mexico, unaware of the false or fraudulent nature of these claims, paid such claims which the State of New Mexico would not otherwise have paid.

289. By reason of these payments, the State of New Mexico has been damaged, and continues to be damaged, in a substantial amount.

**COUNT 26 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE NEW YORK FALSE CLAIMS ACT,
N.Y. FIN. LAW §§ 187 – 194**

290. This is a claim for treble damages and civil penalties under the New York False Claims Act, N.Y. Fin. Law §§ 187 – 194. Relator realleges and incorporates the allegations in

the preceding paragraphs as if set forth fully herein.

291. Defendants violated the New York False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of New York, as described herein.

292. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of New York.

293. The State of New York, unaware of the false or fraudulent nature of these claims, paid such claims which the State of New York would not otherwise have paid.

294. By reason of these payments, the State of New York has been damaged, and continues to be damaged, in a substantial amount.

COUNT 27 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE NORTH CAROLINA FALSE CLAIMS ACT,
N.C. GEN. STAT. ANN. §§ 1-605 – 1-618

295. This is a claim for treble damages and civil penalties under the North Carolina False Claims Act, N.C. Gen. Stat. Ann. §§ 1-605 – 1-618. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

296. Defendants violated the North Carolina False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of North Carolina, as described herein.

297. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of North Carolina.

298. The State of North Carolina, unaware of the false or fraudulent nature of these

claims, paid such claims which the State of North Carolina would not otherwise have paid.

299. By reason of these payments, the State of North Carolina has been damaged, and continues to be damaged, in a substantial amount.

COUNT 28 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE OKLAHOMA MEDICAID FALSE CLAIMS ACT,
OKL. STAT. ANN. TIT. 63, §§ 5053 – 5054

300. This is a claim for treble damages and civil penalties under the Oklahoma Medicaid False Claims Act, Okl. Stat. tit. 63, §§ 5053 – 5054. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

301. Defendants violated the Oklahoma Medicaid False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Oklahoma, as described herein.

302. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Oklahoma.

303. The State of Oklahoma, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Oklahoma would not otherwise have paid.

304. By reason of these payments, the State of Oklahoma has been damaged, and continues to be damaged, in a substantial amount.

COUNT 29 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE RHODE ISLAND STATE FALSE CLAIMS ACT,
R.I. GEN. LAWS ANN. §§ 9-1.1-1 – 9-1.1-9

305. This is a claim for treble damages and civil penalties under the Rhode Island State False Claims Act, R.I. Gen. Laws Ann. §§ 9-1.1-1 – 9-1.1-9. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

306. Defendants violated the Rhode Island State False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Rhode Island, as described herein.

307. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Rhode Island.

308. The State of Rhode Island, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Rhode Island would not otherwise have paid.

309. By reason of these payments, the State of Rhode Island has been damaged, and continues to be damaged, in a substantial amount.

COUNT 30 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE TENNESSEE FALSE CLAIMS ACT,
TENN. CODE ANN. §§ 4-18-101 – 4-18-108
AND THE TENNESSEE MEDICAID FALSE CLAIMS ACT,
TENN. CODE. ANN. §§ 71-5-181 – 71-5-185

310. This is a claim for treble damages and civil penalties under the Tennessee False Claims Act, Tenn. Code Ann. §§ 4-18-101 – 4-18-108, and the Tennessee Medicaid False Claims Act, Tenn. Code. Ann. §§ 71-5-181 – 71-5-185. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

311. Defendants violated the Tennessee False Claims Act and the Tennessee Medicaid False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Tennessee, as described herein.

312. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Tennessee.

313. The State of Tennessee, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Tennessee would not otherwise have paid.

314. By reason of these payments, the State of Tennessee has been damaged, and continues to be damaged, in a substantial amount.

COUNT 31 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE TEXAS MEDICAID FRAUD PREVENTION LAW,
TEX. HUM. RES. CODE ANN. §§ 36.001 – 36.132

315. This is a claim for treble damages and civil penalties under the Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. §§ 36.001 – 36.132. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

316. Defendants violated the Texas Medicaid Fraud Prevention Law by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Texas, as described herein.

317. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Texas.

318. The State of Texas, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Texas would not otherwise have paid.

319. By reason of these payments, the State of Texas has been damaged, and continues to be damaged, in a substantial amount.

COUNT 32 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE VERMONT FALSE CLAIMS ACT,
VT. STAT. ANN. TIT. 32, §§ 630 – 642

320. This is a claim for treble damages and civil penalties under the Vermont False Claims Act, Vt. Stat. Ann. tit. 32, §§ 630 – 642. Relator realleges and incorporates the

allegations in the preceding paragraphs as if set forth fully herein.

321. Defendants violated the Vermont False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State as Vermont, as described herein.

322. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Vermont.

323. The State of Vermont, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Vermont would not otherwise have paid.

324. By reason of these payments, the State of Vermont has been damaged, and continues to be damaged, in a substantial amount.

COUNT 33 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE VIRGINIA FRAUD AGAINST TAXPAYERS ACT,
VA. CODE ANN. §§ 8.01-216.1 – 8.01-216.19

325. This is a claim for treble damages and civil penalties under the Virginia Fraud Against Taxpayers Act, Va. Code Ann. §§ 8.01-216.1 – 8.01-216.19. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

326. Defendants violated the Virginia Fraud Against Taxpayers Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the Commonwealth of Virginia, as described herein.

327. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Commonwealth of Virginia.

328. The Commonwealth of Virginia, unaware of the false or fraudulent nature of

these claims, paid such claims which the Commonwealth of Virginia would not otherwise have paid.

329. By reason of these payments, the Commonwealth of Virginia has been damaged, and continues to be damaged, in a substantial amount.

COUNT 34 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE WASHINGTON MEDICAID FRAUD FALSE CLAIMS ACT, WASH. REV. CODE ANN. §§ 74.66.005 – 74.66.130

330. This is a claim for treble damages and civil penalties under the Washington Medicaid Fraud False Claims Act, Wash. Rev. Code Ann. §§ 74.66.005 – 74.66.130. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

331. Defendants violated the Washington Medicaid Fraud False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Washington, as described herein.

332. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Washington.

333. The State of Washington, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Washington would not otherwise have paid.

334. By reason of these payments, the State of Washington has been damaged, and continues to be damaged, in a substantial amount.

PRAYER FOR RELIEF

WHEREFORE, Relator requests that judgment be entered against Defendants as follows:

(a) treble the Government's damages in an amount determined at trial, plus the maximum statutorily-allowed penalty for each false claim submitted in violation of the FCA or State statute set forth above;

(b) the applicable administrative civil penalties for each violation of the AKS and State-equivalent statute, as well as an assessment of not more than three times the amount of remuneration offered, paid, solicited or received, without regard to whether a portion of that amount was offered, paid or received for a lawful purpose;

(c) an award of costs and the maximum Relator award allowed pursuant to the FCA and State statutes set forth above; and

(d) such further relief as is proper.

Dated: January 12, 2018

Respectfully submitted,

/s/ Sam Baxter

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ATTORNEYS FOR RELATOR

CERTIFICATE OF SERVICE

I certify that the **FIRST AMENDED COMPLAINT** was served upon all counsel of record via the Court's CM/ECF electronic filing system in accordance with the Federal Rules of Civil Procedure and Local Rule CV-5(a) on January 12, 2018. I arranged for service on the Plaintiff States as detailed below:

By U.S. Mail:

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New York Attorney General	Eric Schneiderman Attorney General Attention: MFCU: False Claims Office of the New York State Attorney General Managing Clerk's Office 120 Broadway, 24th Floor New York, NY 10271
North Carolina Attorney General	Josh Stein Attorney General 9001 Mail Service Center Raleigh, NC 27699-9001
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/s/ Samuel Baxter